

## **Section S1. IonTorrent® Oncomine™ Reports used to identify druggable targets**

Druggable targets identified in *ATM*, *BRCA1/2*, *CDK12*, *CHEK1*, *EGFR*, *FGFR3* and *PIK3CA*.

Clinical trials and grading of evidence for the mutations are available in the reports.

The reports are from 25<sup>th</sup> November 2021.

## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>ATM mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<i>ATM splice site mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<i>ATM truncating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<i>ATM deletion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	24
<i>ATM fusion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	12
<i>ATM aberration</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	11

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](http://www.fda.gov).

### ATM mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** ATM mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## ATM splice site mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** ATM mutation

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- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## ATM truncating mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** ATM mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### ATM mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer    **Variant class:** ATM mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer    **Variant class:** ATM mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ATM splice site mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer    **Variant class:** ATM mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer    **Variant class:** ATM mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## ATM truncating mutation

### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** ATM mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

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### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** ATM mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

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## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### ATM mutation + ATM splice site mutation + ATM truncating mutation + ATM deletion

#### NCT04276376

A Multicenter, Open Label, Phase II Basket Trial Exploring the Efficacy And Safety of The Combination of Rucaparib (PARP Inhibitor) And Atezolizumab (Anti-PD-L1 Antibody) In Patients With DNA Repair-Deficient or Platinum-Sensitive Solid Tumors

**Cancer type:** Bladder Urothelial Carcinoma, Non-Small Cell Lung Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant classes:** ATM deletion & ATM mutation

**Other identifiers:** 2018/2727, ARIANES, EudraCT Number: 2018-001744-62

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ATM deletion (Breast Cancer, Ovarian Cancer), ATM mutation (Breast Cancer, Ovarian Cancer), BARD1 deletion (Breast Cancer, Ovarian Cancer), BARD1 mutation (Breast Cancer, Ovarian Cancer), BRCA1 germline deletion (Breast Cancer, Ovarian Cancer), BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline deletion (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer), BRIP1 deletion (Breast Cancer, Ovarian Cancer), BRIP1 mutation (Breast Cancer, Ovarian Cancer), CDK12 deletion (Breast Cancer, Ovarian Cancer), CDK12 mutation (Breast Cancer, Ovarian Cancer), CHEK2 deletion (Breast Cancer, Ovarian Cancer), CHEK2 mutation (Breast Cancer, Ovarian Cancer), FANCA deletion (Breast Cancer, Ovarian Cancer), FANCA mutation (Breast Cancer, Ovarian Cancer), NBN deletion (Breast Cancer, Ovarian Cancer), NBN mutation (Breast Cancer, Ovarian Cancer), PALB2 deletion (Breast Cancer, Ovarian Cancer), PALB2 mutation (Breast Cancer, Ovarian Cancer), RAD51 deletion (Breast Cancer, Ovarian Cancer), RAD51 mutation (Breast Cancer, Ovarian Cancer), RAD51C deletion (Breast Cancer, Ovarian Cancer), RAD51C mutation (Breast Cancer, Ovarian Cancer), RAD51D deletion (Breast Cancer, Ovarian Cancer), RAD51D mutation (Breast Cancer, Ovarian Cancer), RAD54L deletion (Breast Cancer, Ovarian Cancer), RAD54L mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** rucaparib, atezolizumab

**Location:** France

#### NCT04095273

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant classes:** ATM deletion & ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]



## ATM mutation + ATM splice site mutation + ATM truncating mutation + ATM deletion (continued)

### NCT04126070

A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors

**Cancer type:** Prostate Cancer

**Variant classes:** DNA repair deletion & DNA repair mutation

**Other identifiers:** 19-384, NCI-2020-02149

**Population segments:** First line, Stage IV

**Phase:** II

**Therapies:** nivolumab, chemotherapy, hormone therapy

**Location:** United States

**US State:** MA

**Contact:** Dr. Xiao X. Wei [617-632-4524; xiaox\_wei@dfci.harvard.edu]

## ATM mutation

### NCT03682289

Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies

**Cancer type:** Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ATM underexpression

**Other identifiers:** 18-25513, 189510, NCI-2018-01648

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US State:** CA

**Contact:** Erika Zigman [877-837-3222; cancertrials@ucsf.edu]

### NCT04564027

A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)

**Cancer type:** Castration-Resistant Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** D5339C00001, EudraCT Number: 2020-002529-27, PLANETTE

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ATM mutation (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US States:** CA, FL, IN, MI, NV, PA, SC

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

## ATM mutation (continued)

### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

## ATM mutation (continued)

**NCT02693535**

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** ATM mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

## ATM mutation (continued)

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03611868**

A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** TP53 wild type

**Other identifiers:** 2020-0136, APG-115-US-002, Keynote MK-3475-B66, NCI-2019-08846

**Population segments:** Adenocarcinoma, Fourth line or greater, STK11, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant class:** FGFR fusion (Bladder Urothelial Carcinoma)

**Phase:** I/II

**Therapies:** alrizomadlin, pembrolizumab

**Locations:** Australia, United States

**US States:** AR, AZ, CA, DC, FL, MO, NY, PA, TN, TX, VA

**Contact:** Kathryn Shantz [301-802-3414; [kate.shantz@ascentage.com](mailto:kate.shantz@ascentage.com)]

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM mutation (continued)

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## ATM mutation (continued)

### NCT03415659

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

### NCT03767075

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, M039164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

### NCT04905914

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## ATM mutation (continued)

### NCT04901702

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03233204

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]



## ATM mutation (continued)

### NCT03810105

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

### NCT04336943

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## ATM mutation (continued)

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## ATM mutation (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** ATM mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## ATM mutation (continued)

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

### NCT03375307

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03786796

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** ATM mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

## ATM mutation (continued)

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** ATM mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; [hkindler@medicine.bsd.uchicago.edu](mailto:hkindler@medicine.bsd.uchicago.edu)]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; [GUTrials@ucsf.edu](mailto:GUTrials@ucsf.edu)]

## ATM mutation (continued)

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** ATM mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

## ATM mutation (continued)

### NCT04253262

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

### NCT04095273

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

### NCT04169841

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

## ATM mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]



## ATM mutation (continued)

### NCT02264678

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

### NCT04890613

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

### NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## ATM mutation (continued)

### NCT03395197

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCURI017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

### NCT04821622

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

### NCT04038502

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## ATM mutation (continued)

### No NCT ID - see other identifier(s)

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## ATM splice site mutation

### NCT03682289

Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies

**Cancer type:** Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ATM underexpression

**Other identifiers:** 18-25513, 189510, NCI-2018-01648

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US State:** CA

**Contact:** Erika Zigman [877-837-3222; cancertrials@ucsf.edu]

## ATM splice site mutation (continued)

**NCT04564027**

A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)

**Cancer type:** Castration-Resistant Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** D5339C00001, EudraCT Number: 2020-002529-27, PLANETTE

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ATM mutation (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US States:** CA, FL, IN, MI, NV, PA, SC

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## ATM splice site mutation (continued)

**NCT03967938**

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

**NCT02693535**

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** ATM mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

## ATM splice site mutation (continued)

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03611868**

A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** TP53 wild type

**Other identifiers:** 2020-0136, APG-115-US-002, Keynote MK-3475-B66, NCI-2019-08846

**Population segments:** Adenocarcinoma, Fourth line or greater, STK11, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant class:** FGFR fusion (Bladder Urothelial Carcinoma)

**Phase:** I/II

**Therapies:** alrizomadlin, pembrolizumab

**Locations:** Australia, United States

**US States:** AR, AZ, CA, DC, FL, MO, NY, PA, TN, TX, VA

**Contact:** Kathryn Shantz [301-802-3414; kate.shantz@ascentage.com]

## ATM splice site mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral  $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]



## ATM splice site mutation (continued)

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]



## ATM splice site mutation (continued)

### NCT04901702

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03233204

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM splice site mutation (continued)

### NCT04267939

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

### NCT04693468

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

### NCT03810105

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** ATM splice site mutation or DNA repair splice site mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## ATM splice site mutation (continued)

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## ATM splice site mutation (continued)

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## ATM splice site mutation (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** ATM mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## ATM splice site mutation (continued)

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

### NCT03375307

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03786796

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** ATM mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

## ATM splice site mutation (continued)

### NCT04042831

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04515836

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** ATM mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; [hkindler@medicine.bsd.uchicago.edu](mailto:hkindler@medicine.bsd.uchicago.edu)]

### NCT04633902

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

### NCT03248570

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; [GUTrials@ucsf.edu](mailto:GUTrials@ucsf.edu)]

## ATM splice site mutation (continued)

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** ATM mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong



## ATM splice site mutation (continued)

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

## ATM splice site mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

## ATM splice site mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## ATM splice site mutation (continued)

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCURI017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## ATM splice site mutation (continued)

### No NCT ID - see other identifier(s)

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## ATM truncating mutation

### NCT04550494

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM truncating mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM truncating mutation (continued)

**NCT03682289**

Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies

**Cancer type:** Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ATM underexpression

**Other identifiers:** 18-25513, 189510, NCI-2018-01648

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US State:** CA

**Contact:** Erika Zigman [877-837-3222; cancertrials@ucsf.edu]

**NCT04564027**

A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)

**Cancer type:** Castration-Resistant Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** D5339C00001, EudraCT Number: 2020-002529-27, PLANETTE

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ATM mutation (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** ceralasertib

**Location:** United States

**US States:** CA, FL, IN, MI, NV, PA, SC

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProFiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

## ATM truncating mutation (continued)

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## ATM truncating mutation (continued)

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** ATM mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

**NCT03611868**

A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other inclusion criteria:** TP53 wild type

**Other identifiers:** 2020-0136, APG-115-US-002, Keynote MK-3475-B66, NCI-2019-08846

**Population segments:** Adenocarcinoma, Fourth line or greater, STK11, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant class:** FGFR fusion (Bladder Urothelial Carcinoma)

**Phase:** I/II

**Therapies:** alrizomadlin, pembrolizumab

**Locations:** Australia, United States

**US States:** AR, AZ, CA, DC, FL, MO, NY, PA, TN, TX, VA

**Contact:** Kathryn Shantz [301-802-3414; kate.shantz@ascentage.com]



## ATM truncating mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral  $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** ATM mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## ATM truncating mutation (continued)

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

### NCT03415659

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

### NCT03767075

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

### NCT04905914

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## ATM truncating mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM truncating mutation (continued)

### NCT04267939

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

### NCT04693468

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

### NCT03810105

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** ATM truncating mutation or ATM mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## ATM truncating mutation (continued)

### NCT03840967

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** ATM truncating mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

### NCT02975934

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

### NCT04336943

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

## ATM truncating mutation (continued)

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

## ATM truncating mutation (continued)

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## ATM truncating mutation (continued)

### NCT04187833

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

### NCT03375307

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## ATM truncating mutation (continued)

### NCT03786796

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** ATM mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

### NCT04042831

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** ATM mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04515836

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** ATM mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

### NCT04633902

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** ATM mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

## ATM truncating mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

## ATM truncating mutation (continued)

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** ATM mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer

**Variant class:** ATM mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

## ATM truncating mutation (continued)

### NCT04169841

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/ Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

### NCT04940637

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

### NCT04939662

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

## ATM truncating mutation (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## ATM truncating mutation (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIRO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## ATM truncating mutation (continued)

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## ATM deletion

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM deletion

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT02286687

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** ATM deletion

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]



## ATM deletion (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM deletion (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** ATM deletion

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## ATM deletion (continued)

### NCT03012321

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM deletion

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

### NCT03840967

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** ATM deletion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

### NCT04030559

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** ATM deletion

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## ATM deletion (continued)

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** ATM deletion

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

### NCT04633902

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** ATM deletion

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

### NCT03248570

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** ATM deletion

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

## ATM deletion (continued)

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** ATM deletion

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**No NCT ID - see other identifier(s)**

An Open-label, Single-arm Phase Ia/Ib Clinical Study: Phase Ia Dose Exploration Study to Evaluate the SC0245 Tablets in Patients with Advanced Malignant Solid Tumor, and Phase Ib Clinical Study in Gastric Cancer Patients with ATM Deficiency and Esophageal Carcinoma Patients with p53 Mutation

**Cancer type:** Gastric Cancer

**Variant class:** ATM deletion

**Other identifiers:** ChiCTR2100045406, CTR20210769, SC0245-001

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** SC0245

**Location:** China

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAparib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

## ATM deletion (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## ATM fusion

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## ATM fusion (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## ATM fusion (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** ATM fusion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]



## ATM fusion (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## ATM fusion (continued)

### NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## ATM aberration

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ATM aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

### NCT04901702

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## ATM aberration (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

## ATM aberration (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** ATM aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

## ATM aberration (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>ATM mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<b>ATM splice site mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<b>ATM truncating mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	61
<b>ATM deletion</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	24

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>ATM fusion</i> Prognostic significance: None Diagnostic significance: None	None	None	12
<i>ATM aberration</i> Prognostic significance: None Diagnostic significance: None	None	None	11

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

● In this cancer type    
 ○ In other cancer type    
 ◐ In this cancer type and other cancer types    
 × No evidence

### ATM mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	×	×	◐ (II)
olaparib, pembrolizumab	×	×	×	×	◐ (II)
talazoparib	×	×	×	×	◐ (II)
talazoparib, chemotherapy	×	×	×	×	◐ (II)
atezolizumab	×	×	×	×	● (II)
ceralasertib	×	×	×	×	● (II)
olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib	×	×	×	×	● (II)
rucaparib, atezolizumab	×	×	×	×	● (II)
alrizomadlin, pembrolizumab	×	×	×	×	● (I/II)
ATRN-119	×	×	×	×	● (I/II)
RP-3500, talazoparib	×	×	×	×	● (I/II)
BAY-1895344, niraparib	×	×	×	×	● (I)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
HWH-340	×	×	×	×	● (I)
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
rucaparib, hormone therapy	×	×	×	×	○ (III)
talazoparib, hormone therapy	×	×	×	×	○ (III)
durvalumab, olaparib	×	×	×	×	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### ATM mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### ATM splice site mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	● (II)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
ceralasertib	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### ATM splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
alrizomadlin, pembrolizumab	✕	✕	✕	✕	● (I/II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
rucaparib, hormone therapy	✕	✕	✕	✕	○ (III)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### ATM splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### ATM truncating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	● (II)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
ceralasertib	✕	✕	✕	✕	● (II)
olaparib, ipilimumab + nivolumab, atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
alrizomadlin, pembrolizumab	✕	✕	✕	✕	● (I/II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
rucaparib, hormone therapy	✕	✕	✕	✕	○ (III)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### ATM truncating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### ATM deletion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

☒ In this cancer type   
 ☐ In other cancer type   
 ☒ In this cancer type and other cancer types   
 ✕ No evidence

### ATM deletion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
niraparib	✕	✕	✕	✕	<input type="radio"/> (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	<input type="radio"/> (II)
olaparib, pembrolizumab	✕	✕	✕	✕	<input type="radio"/> (II)
pembrolizumab	✕	✕	✕	✕	<input type="radio"/> (II)
pembrolizumab, olaparib	✕	✕	✕	✕	<input type="radio"/> (II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	<input type="radio"/> (I)
RP12146	✕	✕	✕	✕	<input type="radio"/> (I)
SC0245	✕	✕	✕	✕	<input type="radio"/> (I)

### ATM fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	<input checked="" type="radio"/> (II)
olaparib	✕	✕	✕	✕	<input checked="" type="radio"/> (II)
RP-3500, talazoparib	✕	✕	✕	✕	<input checked="" type="radio"/> (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	<input checked="" type="radio"/> (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	<input checked="" type="radio"/> (I)
niraparib	✕	✕	✕	✕	<input type="radio"/> (II)
olaparib, pembrolizumab	✕	✕	✕	✕	<input type="radio"/> (II)
pembrolizumab	✕	✕	✕	✕	<input type="radio"/> (II)
pembrolizumab, olaparib	✕	✕	✕	✕	<input type="radio"/> (II)
RP12146	✕	✕	✕	✕	<input type="radio"/> (I)

### ATM aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	<input checked="" type="radio"/> (II)
olaparib	✕	✕	✕	✕	<input checked="" type="radio"/> (II)
RP-3500, talazoparib	✕	✕	✕	✕	<input checked="" type="radio"/> (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	<input checked="" type="radio"/> (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	<input checked="" type="radio"/> (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types
 ☒ No evidence

### ATM aberration (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib, pembrolizumab	×	×	×	×	○ (II)
pembrolizumab	×	×	×	×	○ (II)
pembrolizumab, olaparib	×	×	×	×	○ (II)
RP12146	×	×	×	×	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>ATM mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	61
<b>ATM splice site mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	61
<b>ATM truncating mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	61
<b>ATM deletion</b> Prognostic significance: None Diagnostic significance: None	None	None	24
<b>ATM fusion</b> Prognostic significance: None Diagnostic significance: None	None	None	12
<b>ATM aberration</b> Prognostic significance: None Diagnostic significance: None	None	None	11

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### ATM mutation + ATM splice site mutation + ATM truncating mutation + ATM deletion

NCT ID	Title	Phase
NCT04276376	A Multicenter, Open Label, Phase II Basket Trial Exploring the Efficacy And Safety of The Combination of Rucaparib (PARP Inhibitor) And Atezolizumab (Anti-PD-L1 Antibody) In Patients With DNA Repair-Deficient or Platinum-Sensitive Solid Tumors	II

**Disclaimer:** The data presented here is from a curated knowledgebase of publicly available information, but may not be exhaustive. The data version is 2021.11(003).

## Clinical Trials Summary (continued)

### ATM mutation + ATM splice site mutation + ATM truncating mutation + ATM deletion (continued)

NCT ID	Title	Phase
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04126070	A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors	II

### ATM mutation

NCT ID	Title	Phase
NCT03682289	Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies	II
NCT04564027	A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)	II
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03611868	A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors	I/II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II

## Clinical Trials Summary (continued)

### ATM mutation (continued)

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II

## Clinical Trials Summary (continued)

### ATM mutation (continued)

NCT ID	Title	Phase
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I

## Clinical Trials Summary (continued)

### ATM mutation (continued)

NCT ID	Title	Phase
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### ATM splice site mutation

NCT ID	Title	Phase
NCT03682289	Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies	II
NCT04564027	A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)	II
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II



## Clinical Trials Summary (continued)

### ATM splice site mutation (continued)

NCT ID	Title	Phase
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03611868	A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors	I/II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II

## Clinical Trials Summary (continued)

### ATM splice site mutation (continued)

NCT ID	Title	Phase
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II

## Clinical Trials Summary (continued)

### ATM splice site mutation (continued)

NCT ID	Title	Phase
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### ATM truncating mutation

NCT ID	Title	Phase
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03682289	Phase II Trial of AZD6738 Alone and in Combination With Olaparib in Patients With Selected Solid Tumor Malignancies	II
NCT04564027	A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients With Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)	II
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II

## Clinical Trials Summary (continued)

### ATM truncating mutation (continued)

NCT ID	Title	Phase
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT03611868	A Phase Ib/II Study of APG-115 in Combination With Pembrolizumab in Patients With Unresectable or Metastatic Melanomas or Advanced Solid Tumors	I/II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I

## Clinical Trials Summary (continued)

### ATM truncating mutation (continued)

NCT ID	Title	Phase
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II
NCT03012321	BRCAaway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II

## Clinical Trials Summary (continued)

### ATM truncating mutation (continued)

NCT ID	Title	Phase
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPARIB (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II



## Clinical Trials Summary (continued)

### ATM deletion

NCT ID	Title	Phase
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
No NCT ID	An Open-label, Single-arm Phase Ia/Ib Clinical Study: Phase Ia Dose Exploration Study to Evaluate the SC0245 Tablets in Patients with Advanced Malignant Solid Tumor, and Phase Ib Clinical Study in Gastric Cancer Patients with ATM Deficiency and Esophageal Carcinoma Patients with p53 Mutation	I
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II

## Clinical Trials Summary (continued)

### ATM deletion (continued)

NCT ID	Title	Phase
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### ATM fusion

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I



## Clinical Trials Summary (continued)

### ATM aberration

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>BRCA1 mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<i>BRCA1 splice site mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<i>BRCA1 truncating mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<i>BRCA1 deletion</i>  Prognostic significance: None Diagnostic significance: None	None	None	21
<i>BRCA1 fusion</i>  Prognostic significance: None Diagnostic significance: None	None	None	16
<i>BRCA1 aberration</i>  Prognostic significance: None Diagnostic significance: None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

### BRCA1 mutation

#### ☐ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA1 mutation

#### Indications and usage:

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA1 mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA1 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## BRCA1 mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA1 mutation

#### Indications and usage:

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

#### Prostate cancer

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)

## BRCA1 splice site mutation

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA1 mutation

#### Indications and usage:

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA1 splice site mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA1 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## BRCA1 splice site mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA1 mutation

**Indications and usage:**

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

**Ovarian cancer**

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

**Prostate cancer**

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)

## BRCA1 truncating mutation

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA1 mutation

**Indications and usage:**

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA1 truncating mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA1 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)



## BRCA1 truncating mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA1 mutation

**Indications and usage:**

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

Ovarian cancer

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

Prostate cancer

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BRCA1 mutation

#### ☐ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA1 mutation (continued)

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA1 splice site mutation

### ○ bevacizumab + olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

**Reference:** NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 splice site mutation (continued)

### ☐ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ☐ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ☐ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ☐ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA1 splice site mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 splice site mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]



## BRCA1 truncating mutation

### ○ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 truncating mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA1 truncating mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA1 truncating mutation (continued)

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## Current EMA Information

- ☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

EMA information is current as of 2021-10-13. For the most up-to-date information, search [www.ema.europa.eu/ema](http://www.ema.europa.eu/ema).

### BRCA1 mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA1 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

#### ☐ rucaparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-09-20

**Variant class:** BRCA1 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

### BRCA1 splice site mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA1 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

#### ☐ rucaparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-09-20

**Variant class:** BRCA1 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

### BRCA1 truncating mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA1 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

## BRCA1 truncating mutation (continued)

### ☐ rucaparib

Cancer type: Ovarian Cancer

Label as of: 2021-09-20

Variant class: BRCA1 mutation

Reference:

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

## Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2021-10-01. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### BRCA1 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA1 mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / B

**Population segment (Line of therapy):**

- Metastatic, Progression (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

#### ☐ bevacizumab + olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

#### ☐ niraparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

#### ☐ olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA1 mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Epithelial; Recurrent (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA1 splice site mutation

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Metastatic, Progression (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

### ○ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]



## BRCA1 splice site mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Epithelial; Recurrent (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA1 truncating mutation

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA1 mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Metastatic, Progression (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

### ○ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA1 truncating mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: III / A


Population segment (Line of therapy):


- Epithelial; Recurrent (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]


## Alerts Informed By Public Data Sources

### Current NCCN Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BRCA1 mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### BRCA1 splice site mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### BRCA1 truncating mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### BRCA1 mutation + BRCA1 splice site mutation + BRCA1 truncating mutation + BRCA1 deletion

#### NCT04126070

A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors

**Cancer type:** Prostate Cancer

**Variant classes:** DNA repair deletion & DNA repair mutation

**Other identifiers:** 19-384, NCI-2020-02149

**Population segments:** First line, Stage IV

**Phase:** II

**Therapies:** nivolumab, chemotherapy, hormone therapy

**Location:** United States

**US State:** MA

**Contact:** Dr. Xiao X. Wei [617-632-4524; xiaox\_wei@dfci.harvard.edu]

### BRCA1 mutation

#### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

#### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

## BRCA1 mutation (continued)

**NCT02693535**

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

## BRCA1 mutation (continued)

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

## BRCA1 mutation (continued)

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; askmdanderson@mdanderson.org]

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA1 mutation (continued)

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, M039164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]



## BRCA1 mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

## BRCA1 mutation (continued)

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## BRCA1 mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA1 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## BRCA1 mutation (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## BRCA1 mutation (continued)

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

### NCT03375307

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## BRCA1 mutation (continued)

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA1 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 mutation (continued)

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With Olaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]



## BRCA1 mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]

## BRCA1 mutation (continued)

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA1 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]

## BRCA1 mutation (continued)

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## BRCA1 mutation (continued)

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

## BRCA1 mutation (continued)

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@pennmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

## BRCA1 mutation (continued)

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

## BRCA1 mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## BRCA1 mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCURO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]



## BRCA1 mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## BRCA1 mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA1 splice site mutation

### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## BRCA1 splice site mutation (continued)

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 splice site mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; [askmdanderson@mdanderson.org](mailto:askmdanderson@mdanderson.org)]

## BRCA1 splice site mutation (continued)

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**BRCA1 splice site mutation (continued)****NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## BRCA1 splice site mutation (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]



## BRCA1 splice site mutation (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA1 splice site mutation or DNA repair splice site mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

## BRCA1 splice site mutation (continued)

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

## BRCA1 splice site mutation (continued)

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA1 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

## BRCA1 splice site mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## BRCA1 splice site mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## BRCA1 splice site mutation (continued)

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA1 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 splice site mutation (continued)

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With Olaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

## BRCA1 splice site mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]



## BRCA1 splice site mutation (continued)

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA1 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]

## BRCA1 splice site mutation (continued)

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## BRCA1 splice site mutation (continued)

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

## BRCA1 splice site mutation (continued)

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@pennmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

## BRCA1 splice site mutation (continued)

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

## BRCA1 splice site mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## BRCA1 splice site mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCURO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## BRCA1 splice site mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China



## BRCA1 splice site mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA1 truncating mutation

### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## BRCA1 truncating mutation (continued)

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 truncating mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; [askmdanderson@mdanderson.org](mailto:askmdanderson@mdanderson.org)]

## BRCA1 truncating mutation (continued)

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## BRCA1 truncating mutation (continued)

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## BRCA1 truncating mutation (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

## BRCA1 truncating mutation (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA1 truncating mutation or BRCA1 mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA1 truncating mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]



## BRCA1 truncating mutation (continued)

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## BRCA1 truncating mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA1 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## BRCA1 truncating mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## BRCA1 truncating mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## BRCA1 truncating mutation (continued)

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA1 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA1 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 truncating mutation (continued)

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With Olaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA1 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

## BRCA1 truncating mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]

## BRCA1 truncating mutation (continued)

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA1 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]



## BRCA1 truncating mutation (continued)

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA1 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA1 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## BRCA1 truncating mutation (continued)

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA1 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

## BRCA1 truncating mutation (continued)

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@pennmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

## BRCA1 truncating mutation (continued)

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

## BRCA1 truncating mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; [mdallera@ucdavis.edu](mailto:mdallera@ucdavis.edu)]

## BRCA1 truncating mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCURO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## BRCA1 truncating mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

**BRCA1 truncating mutation (continued)****NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]



## BRCA1 deletion

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA1 deletion

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA1 deletion (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**BRCA1 deletion (continued)****NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA1 deletion

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## BRCA1 deletion (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 deletion

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA1 deletion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA1 deletion

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

## BRCA1 deletion (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA1 deletion

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA1 deletion

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAparib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR deletion

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## BRCA1 deletion (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair deletion

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA1 deletion (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## BRCA1 fusion

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA1 fusion (continued)

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** Fanconi anemia pathway

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## BRCA1 fusion (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## BRCA1 fusion (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA1 fusion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT02502266**

A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women With Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA fusion

**Other identifiers:** 16-715, COCOS, GY005, GY005-, GYN 9814, jRCT2031190097, KCT0004526, N 33516, NCI-2015-00651, NRG OV1405, NRG-GY005, OVC2, OVM1405, S16-01681

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** II/III

**Therapies:** cediranib, olaparib

**Locations:** Japan, United States

**US State:** SD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04739800**

A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor (Durvalumab) MEDI4736 in Combination With Olaparib and Cediranib) Compared to Olaparib and Cediranib or (Durvalumab) MEDI4736 and Cediranib or Standard of Care Chemotherapy in Women With Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA fusion

**Other identifiers:** NCI-2021-00615, NRG-GY023

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** durvalumab, olaparib, cediranib

**Location:** United States

**US States:** CA, GA, IA, ID, IL, MD, ME, MN, MO, MT, NC, NE, NV, NY, OH, OK, OR, PA, RI, TN, TX, WA, WI, WV

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 fusion (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA1 fusion (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## BRCA1 aberration

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA1 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA1 aberration (continued)

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variation class:** Fanconi anemia pathway

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variation class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variation class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA1 aberration (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## BRCA1 aberration (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA1 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA1 aberration (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>BRCA1 mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 splice site mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 truncating mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 deletion</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	21
<b>BRCA1 fusion</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	16
<b>BRCA1 aberration</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	13

Public data sources included in relevant therapies: FDA1, NCCN, EMA2, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO



## Relevant Therapy Summary

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 × No evidence

### BRCA1 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	● (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	×
niraparib	○	○	×	○	○ (III)
olaparib, pembrolizumab	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
talazoparib, chemotherapy	×	×	×	×	● (II)
atezolizumab	×	×	×	×	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	×	×	×	×	● (II)
ATRN-119	×	×	×	×	● (I/II)
RP-3500, talazoparib	×	×	×	×	● (I/II)
BAY-1895344, niraparib	×	×	×	×	● (I)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
HWH-340	×	×	×	×	● (I)
olaparib, adavosertib	×	×	×	×	● (I)
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
atezolizumab, chemotherapy, niraparib	×	×	×	×	○ (III)
cediranib, olaparib	×	×	×	×	○ (III)
rucaparib, hormone therapy	×	×	×	×	○ (III)
talazoparib, hormone therapy	×	×	×	×	○ (III)
ceralasertib, olaparib	×	×	×	×	○ (II)
durvalumab, olaparib	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
durvalumab, tremelimumab, olaparib	×	×	×	×	○ (II)
hormone therapy, olaparib, steroid	×	×	×	×	○ (II)
niraparib, dostarlimab	×	×	×	×	○ (II)
nivolumab, chemotherapy, hormone therapy	×	×	×	×	○ (II)
nivolumab, talazoparib	×	×	×	×	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### BRCA1 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
talazoparib, avelumab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA1 splice site mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	ⓘ (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	✕
niraparib	○	○	✕	○	○ (III)
olaparib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
talazoparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
atezolizumab	✕	✕	✕	✕	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### BRCA1 splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
olaparib, adavosertib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
atezolizumab, chemotherapy, niraparib	✕	✕	✕	✕	○ (III)
cediranib, olaparib	✕	✕	✕	✕	○ (III)
rucaparib, hormone therapy	✕	✕	✕	✕	○ (III)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
ceralasertib, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
talazoparib, avelumab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### BRCA1 splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA1 truncating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	● (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	✕
niraparib	○	○	✕	○	○ (III)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
olaparib, adavosertib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
atezolizumab, chemotherapy, niraparib	✕	✕	✕	✕	○ (III)
cediranib, olaparib	✕	✕	✕	✕	○ (III)
rucaparib, hormone therapy	✕	✕	✕	✕	○ (III)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
ceralasertib, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### BRCA1 truncating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
talazoparib, avelumab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA1 deletion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### BRCA1 deletion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA1 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
olaparib	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
cediranib, olaparib	✕	✕	✕	✕	○ (II/III)
durvalumab, olaparib, cediranib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA1 aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
olaparib	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type
  In other cancer type
  In this cancer type and other cancer types
  No evidence

### BRCA1 aberration (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
RP-3500, talazoparib	×	×	×	×	● (I/II)
BAY-1895344, niraparib	×	×	×	×	● (I)
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
olaparib, pembrolizumab	×	×	×	×	○ (II)
pembrolizumab	×	×	×	×	○ (II)
pembrolizumab, olaparib	×	×	×	×	○ (II)
RP12146	×	×	×	×	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>BRCA1 mutation</b>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 splice site mutation</b>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 truncating mutation</b>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	77
<b>BRCA1 deletion</b>  Prognostic significance: None Diagnostic significance: None	None	None	21
<b>BRCA1 fusion</b>  Prognostic significance: None Diagnostic significance: None	None	None	16

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>BRCA1</i> aberration <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	13

Public data sources included in relevant therapies: FDA1, NCCN, EMA2, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### BRCA1 mutation + BRCA1 splice site mutation + BRCA1 truncating mutation + BRCA1 deletion

NCT ID	Title	Phase
NCT04126070	A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors	II

### BRCA1 mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II



## Clinical Trials Summary (continued)

### BRCA1 mutation (continued)

NCT ID	Title	Phase
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II

## Clinical Trials Summary (continued)

### BRCA1 mutation (continued)

NCT ID	Title	Phase
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II

## Clinical Trials Summary (continued)

### BRCA1 mutation (continued)

NCT ID	Title	Phase
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II

## Clinical Trials Summary (continued)

### BRCA1 mutation (continued)

NCT ID	Title	Phase
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### BRCA1 splice site mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II

## Clinical Trials Summary (continued)

### BRCA1 splice site mutation (continued)

NCT ID	Title	Phase
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II

## Clinical Trials Summary (continued)

### BRCA1 splice site mutation (continued)

NCT ID	Title	Phase
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II



## Clinical Trials Summary (continued)

### BRCA1 splice site mutation (continued)

NCT ID	Title	Phase
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II

## Clinical Trials Summary (continued)

### BRCA1 splice site mutation (continued)

NCT ID	Title	Phase
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II



## Clinical Trials Summary (continued)

### BRCA1 truncating mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I

## Clinical Trials Summary (continued)

### BRCA1 truncating mutation (continued)

NCT ID	Title	Phase
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II

## Clinical Trials Summary (continued)

### BRCA1 truncating mutation (continued)

NCT ID	Title	Phase
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III

## Clinical Trials Summary (continued)

### BRCA1 truncating mutation (continued)

NCT ID	Title	Phase
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPARIB (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II

## Clinical Trials Summary (continued)

### BRCA1 truncating mutation (continued)

NCT ID	Title	Phase
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### BRCA1 deletion

NCT ID	Title	Phase
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II

## Clinical Trials Summary (continued)

### BRCA1 deletion (continued)

NCT ID	Title	Phase
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLapaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### BRCA1 fusion

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT02502266	A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women With Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)	II/III



## Clinical Trials Summary (continued)

### BRCA1 fusion (continued)

NCT ID	Title	Phase
NCT04739800	A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor (Durvalumab) MEDI4736 in Combination With Olaparib and Cediranib) Compared to Olaparib and Cediranib or (Durvalumab) MEDI4736 and Cediranib or Standard of Care Chemotherapy in Women With Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### BRCA1 aberration

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II

## Clinical Trials Summary (continued)

### BRCA1 aberration (continued)

NCT ID	Title	Phase
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I



## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>BRCA2 mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<i>BRCA2 splice site mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<i>BRCA2 truncating mutation</i>  Prognostic significance: None Diagnostic significance: None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<i>BRCA2 deletion</i>  Prognostic significance: None Diagnostic significance: None	None	None	21
<i>BRCA2 fusion</i>  Prognostic significance: None Diagnostic significance: None	None	None	16
<i>BRCA2 aberration</i>  Prognostic significance: None Diagnostic significance: None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

### BRCA2 mutation

#### ☐ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA2 mutation

#### Indications and usage:

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA2 mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA2 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## BRCA2 mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA2 mutation

**Indications and usage:**

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

**Ovarian cancer**

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

**Prostate cancer**

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)

## BRCA2 splice site mutation

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA2 mutation

**Indications and usage:**

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA2 splice site mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA2 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## BRCA2 splice site mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA2 mutation

**Indications and usage:**

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

**Ovarian cancer**

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

**Prostate cancer**

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)

## BRCA2 truncating mutation

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-07-27

**Variant class:** BRCA2 mutation

**Indications and usage:**

ZEJULA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, or
  - genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA®.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208447s022s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208447s022s024lbl.pdf)

## BRCA2 truncating mutation (continued)

### ○ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-03-11

**Variant class:** BRCA2 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## BRCA2 truncating mutation (continued)

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-09-30

**Variant class:** BRCA2 mutation

**Indications and usage:**

RUBRACA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

Ovarian cancer

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

Prostate cancer

- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA®.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/209115s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209115s009lbl.pdf)



## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BRCA2 mutation

#### ☐ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

#### ☐ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA2 mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA2 mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA2 mutation (continued)

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA2 splice site mutation

### ○ bevacizumab + olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

**Reference:** NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA2 splice site mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA2 splice site mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA2 splice site mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA2 truncating mutation

### ○ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]



## BRCA2 truncating mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Persistent, Recurrent, Partial response, Complete response (Maintenance therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## BRCA2 truncating mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Fallopian Tube, Primary Peritoneal; Stage II, Stage III, Stage IV; Partial response, Complete response (Maintenance therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Epithelial, Less Common Ovarian Cancers, Fallopian Tube, Primary Peritoneal; Recurrent (Recurrence therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### ○ rucaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## BRCA2 truncating mutation (continued)

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### ○ rucaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## Current EMA Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

EMA information is current as of 2021-10-13. For the most up-to-date information, search [www.ema.europa.eu/ema](http://www.ema.europa.eu/ema).

### BRCA2 mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA2 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

#### ☐ rucaparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-09-20

**Variant class:** BRCA2 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

### BRCA2 splice site mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA2 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

#### ☐ rucaparib

**Cancer type:** Ovarian Cancer

**Label as of:** 2021-09-20

**Variant class:** BRCA2 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

### BRCA2 truncating mutation

#### ☐ olaparib, bevacizumab + olaparib

**Cancer type:** Castration-Resistant Prostate Cancer, Ovarian Cancer

**Label as of:** 2021-10-12

**Variant class:** BRCA2 mutation

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/lynparza-epar-product-information_en.pdf)

## BRCA2 truncating mutation (continued)

### ○ rucaparib

Cancer type: Ovarian Cancer

Label as of: 2021-09-20

Variant class: BRCA2 mutation

Reference:

[https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf)

## Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2021-10-01. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### BRCA2 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / B

**Population segment (Line of therapy):**

- Metastatic, Progression (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

#### ☐ bevacizumab + olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

#### ☐ niraparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

#### ☐ olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA2 mutation (continued)

### ○ rucaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** III / A

**Population segment (Line of therapy):**

- Epithelial; Recurrent (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA2 splice site mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** BRCA2 mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / B

**Population segment (Line of therapy):**

- Metastatic, Progression (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

### ○ bevacizumab + olaparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ niraparib

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA2 splice site mutation (continued)

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Epithelial; Recurrent (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

## BRCA2 truncating mutation

### ○ olaparib

Cancer type: Castration-Resistant Prostate Cancer Variant class: BRCA2 mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Metastatic, Progression (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cancer of the Prostate [Ann Oncol (2020)]

### ○ bevacizumab + olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]



## BRCA2 truncating mutation (continued)

### ○ niraparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ olaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Epithelial; Relapsed (Maintenance therapy); ESMO-MCBS v1.1 score: 4

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]

### ○ rucaparib

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

ESMO Level of Evidence/Grade of Recommendation: III / A


Population segment (Line of therapy):

- Epithelial; Recurrent (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma [Ann Oncol 2013; 24 (Suppl 6): vi24-vi32. (eUpdate: 19 July 2021, 01 April 2020, 21 September 2016; Corrigendum: 03 October 2018)]


## Alerts Informed By Public Data Sources

### Current NCCN Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BRCA2 mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### BRCA2 splice site mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

### BRCA2 truncating mutation

#### bevacizumab

Cancer type: Ovarian Cancer

Variant class: BRCA2 mutation

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "bevacizumab monotherapy is no longer recommended for patients with BRCA1/2 mutations"

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2021]

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### BRCA2 mutation + BRCA2 splice site mutation + BRCA2 truncating mutation + BRCA2 deletion

#### NCT04126070

A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors

**Cancer type:** Prostate Cancer

**Variant classes:** DNA repair deletion & DNA repair mutation

**Other identifiers:** 19-384, NCI-2020-02149

**Population segments:** First line, Stage IV

**Phase:** II

**Therapies:** nivolumab, chemotherapy, hormone therapy

**Location:** United States

**US State:** MA

**Contact:** Dr. Xiao X. Wei [617-632-4524; xiaox\_wei@dfci.harvard.edu]

### BRCA2 mutation

#### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

#### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

## BRCA2 mutation (continued)

**NCT02693535**

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

## BRCA2 mutation (continued)

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

## BRCA2 mutation (continued)

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; askmdanderson@mdanderson.org]

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA2 mutation (continued)

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, M039164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## BRCA2 mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## BRCA2 mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

## BRCA2 mutation (continued)

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## BRCA2 mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA2 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## BRCA2 mutation (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04717154**

Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CA184-585, EudraCT Number: 2020-001240-25, INSPIRE, MOURO048 - INSPIRE, MOURO48

**Population segments:** BRCA, First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** nivolumab, ipilimumab

**Location:** Netherlands

## BRCA2 mutation (continued)

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 mutation (continued)

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 mutation (continued)

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA2 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

## BRCA2 mutation (continued)

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLAparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom



## BRCA2 mutation (continued)

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA2 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

## BRCA2 mutation (continued)

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**BRCA2 mutation (continued)****NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

## BRCA2 mutation (continued)

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

## BRCA2 mutation (continued)

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@pennmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

## BRCA2 mutation (continued)

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

## BRCA2 mutation (continued)

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

## BRCA2 mutation (continued)

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIR017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]



## BRCA2 mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## BRCA2 mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA2 splice site mutation

### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## BRCA2 splice site mutation (continued)

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 splice site mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; [askmdanderson@mdanderson.org](mailto:askmdanderson@mdanderson.org)]

## BRCA2 splice site mutation (continued)

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## BRCA2 splice site mutation (continued)

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## BRCA2 splice site mutation (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]



## BRCA2 splice site mutation (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA2 splice site mutation or DNA repair splice site mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

## BRCA2 splice site mutation (continued)

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

## BRCA2 splice site mutation (continued)

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA2 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

## BRCA2 splice site mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04717154**

Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CA184-585, EudraCT Number: 2020-001240-25, INSPIRE, MOURO048 - INSPIRE, MOURO48

**Population segments:** BRCA, First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** nivolumab, ipilimumab

**Location:** Netherlands

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## BRCA2 splice site mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## BRCA2 splice site mutation (continued)

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA2 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 splice site mutation (continued)

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With Olaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

## BRCA2 splice site mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]



## BRCA2 splice site mutation (continued)

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA2 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]

## BRCA2 splice site mutation (continued)

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

## BRCA2 splice site mutation (continued)

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

## BRCA2 splice site mutation (continued)

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@penndmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

## BRCA2 splice site mutation (continued)

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

## BRCA2 splice site mutation (continued)

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

## BRCA2 splice site mutation (continued)

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIR017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## BRCA2 splice site mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China



## BRCA2 splice site mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA2 truncating mutation

### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapies:** olaparib, talazoparib, atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## BRCA2 truncating mutation (continued)

**NCT04171700**

A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 19-756, 20619, AAAS6974, CO-338-100, LODESTAR, NCI-2019-08226

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US States:** CA, FL, IA, IL, MA, MN, NY, OH, OK, PA, TN, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 truncating mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT04197713**

Phase I Sequential Trial of Agents Against DNA Repair (STAR)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 mutation

**Other identifiers:** (STAR), 10329, 2020-0347, NCI-2019-08262, STAR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** olaparib, adavosertib

**Location:** United States

**US State:** TX

**Contact:** Site Public Contact [877-632-6789; [askmdanderson@mdanderson.org](mailto:askmdanderson@mdanderson.org)]

## BRCA2 truncating mutation (continued)

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## BRCA2 truncating mutation (continued)

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## BRCA2 truncating mutation (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

## BRCA2 truncating mutation (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA2 truncating mutation or BRCA2 mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA2 truncating mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]



## BRCA2 truncating mutation (continued)

**NCT02975934**

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16238, 1723GCCC, 18-146, 18-300, 20171185, 2018IS040, CO-338-063, CSET 2620, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, STAR Trial, TRITON 3\_CO-338-063, TRITON3

**Population segments:** BRCA, First line, Hormone refractory, Stage IV

**Phase:** III

**Therapies:** rucaparib, hormone therapy

**Locations:** Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

**US States:** AZ, CA, CO, CT, DE, FL, HI, MD, MN, NC, NY, OH, OR, TN, TX, VA, WA

**Contact:** Clovis Oncology For North America [844-258-7662; medinfo@clovisoncology.com]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## BRCA2 truncating mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**No NCT ID - see other identifier(s)**

Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer, Uterine Leiomyosarcoma

**Variant class:** BRCA2 mutation

**Other identifiers:** (JGOG2052), jRCT2031210264

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03601923**

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 18-207, NCI-2018-02395

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** MA

**Contact:** Dr. James Cleary [617-632-5960; JCLEARY@PARTNERS.ORG]

## BRCA2 truncating mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04493060**

Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** MC1841, NCI-2020-05352

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04717154**

Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CA184-585, EudraCT Number: 2020-001240-25, INSPIRE, MOURO048 - INSPIRE, MOURO48

**Population segments:** BRCA, First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** nivolumab, ipilimumab

**Location:** Netherlands

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## BRCA2 truncating mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; [Trialsites@merck.com](mailto:Trialsites@merck.com)]

## BRCA2 truncating mutation (continued)

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** BRCA2 mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** BRCA2 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04858334**

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** APOLLO, CTSU/EA2192, EA2192, NCI-2020-05659

**Population segments:** Adjuvant, BRCA, Maintenance/Consolidation, Stage 0, Stage I, Stage II

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, FL, IA, IL, IN, KS, MI, MO, NC, NJ, NM, NV, NY, OH, OR, PA, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 truncating mutation (continued)

**NCT02849496**

A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 10020, 109587 (10020), 1608018258, 17-709, 18979, 5UM1CA186709-04, Clinical Trial 18979, NCI-2016-01130, OSU-17011, PHII-146

**Population segments:** BRCA, HER2 negative, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, atezolizumab

**Location:** United States

**US States:** CA, CO, CT, FL, IL, MA, MD, MI, MO, NC, NY, OH, PA, TN, UT

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT04261465**

The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With Olaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 2317, 2345, EudraCT Number: 2018-002687-65, NUVOLA, NUVOLA trial

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** Italy

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA2 mutation

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)]

## BRCA2 truncating mutation (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04089189**

A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CTR20190652, IMP4297-2018-CN01

**Population segments:** Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** senaparib

**Location:** China

**NCT03990896**

Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

**Cancer type:** Breast Cancer, Triple Negative Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 19-188, NCI-2019-07732

**Population segments:** BRCA, Estrogen receptor positive, Fourth line or greater, HER2 negative, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US States:** MA, TX

**Contact:** Dr. Neelima Vidula [617-724-4000; nvidula@mgh.harvard.edu]

## BRCA2 truncating mutation (continued)

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA2 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT03685331**

Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** (HOPE), NCI-2019-04210, UPCC 21118

**Population segments:** BRCA, Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** olaparib, palbociclib, hormone therapy

**Location:** United States

**US State:** PA

**Contact:** Alexandra Torres [855-216-0098; PennCancerTrials@emergingmed.com]



## BRCA2 truncating mutation (continued)

**No NCT ID - see other identifier(s)**

An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** CeNturlOn, CeNturlOn-2016, EudraCT Number: 2017-004780-13, ISRCTN10490346

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** I/II

**Therapies:** rucaparib, nivolumab, ipilimumab

**Location:** United Kingdom

**NCT03964532**

TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** BRCA2 mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** NCI-2019-06240, STUDY00000023, TALAVE

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapies:** talazoparib, avelumab

**Location:** United States

**US States:** DC, NC, UT

**Contact:** Dr. Julie Collins [202-444-2223; Julie.Collins@gunet.georgetown.edu]

**NCT04673448**

Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer

**Cancer type:** Breast Cancer, Ovarian Cancer, Pancreatic Cancer

**Variant class:** BRCA2 mutation

**Other identifiers:** 10020, NCI-2020-11636, RG1005140

**Population segments:** BRCA, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** niraparib, dostarlimab

**Location:** United States

**US State:** WA

**Contact:** Elizabeth M. Swisher [206-543-3669; swishere@uw.edu]

**NCT04598321**

BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA2 mutation

**Other identifier:** BrUOG 390

**Population segments:** BRCA, Maintenance/Consolidation, Neoadjuvant, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** talazoparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@Brown.edu]

## BRCA2 truncating mutation (continued)

**NCT03598270**

A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** AGO ovary 2.33, ANITA, BGOG-ov-41, ENGOT-ov41, ENGOT-OV41/GEICO 69-O/ANITA, ENGOT-ov41/GEICO/ANITA, ENGOT-Ov41/GEICO69-O/ANITA, EudraCT Number: 2018-000366-11, GEICO 69-O, GEICO-69-O

**Population segments:** (N/A), BRCA, Maintenance/Consolidation, Second line, Third line

**Phase:** III

**Therapies:** atezolizumab, chemotherapy, niraparib

**Locations:** Belgium, France, Germany, Italy, Spain

**NCT03278717**

International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 36280, ACTRN12618000498291, ANZGOG 1415/2018, CRUK/15/074, CTC 0133, ENGOT-ov35, ENGOT-ov35/NCRI/ICON 9, EudraCT Number: 2017-000161-75, ICON9, NC174, OV26 (CRUK/UCL ICON9), UCL/14/0795

**Population segments:** BRCA, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** cediranib, olaparib

**Locations:** Australia, Canada, New Zealand, United Kingdom

**NCT04915755**

A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** 213831, EudraCT Number: 2020-003973-23, GSK 213831 ZEST, SNCTP000004543, ZEST

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** III

**Therapy:** niraparib

**Locations:** Canada, France, Ireland, Italy, Netherlands, Norway, Poland, Russian Federation, Spain, United Kingdom, United States

**US State:** IL

**Contact:** US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

## BRCA2 truncating mutation (continued)

**NCT03462342**

Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA mutation

**Other identifiers:** 20-320, CAPRI, ESR-16-12311, NCI-2018-02375, UPCC 15817

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** ceralasertib, olaparib

**Location:** United States

**US States:** MA, MD, PA

**Contact:** Diego Rodriguez [215-614-0234; diegorod@pennmedicine.upenn.edu]

**No NCT ID - see other identifier(s)**

An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)

**Cancer type:** Cholangiocarcinoma, Colon Cancer, Gastrointestinal Stromal Tumor, Pancreatic Cancer, Rectal Cancer

**Variant class:** BRCA mutation

**Other identifiers:** jRCT2011200023, NIR-B

**Population segments:** BRCA, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** Japan

**NCT04716686**

Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study

**Cancer type:** Endometrial Serous Adenocarcinoma

**Variant class:** BRCA mutation

**Other identifier:** ZL-2306-914

**Population segments:** BRCA, Fourth line or greater, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** China

**NCT04348045**

MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** DPYD wild type

**Other identifiers:** D19-02, EudraCT Number: 2019-004366-18, MAZEPPA D19-02, MAZEPPA D19-02 PRODIGE 72, MAZEPPA\_D19-02, PRODIGY 72 - MAZEPPA

**Population segments:** BRCA, KRAS, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** France

## BRCA2 truncating mutation (continued)

**NCT03025035**

Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** BRCA mutation

**Other identifier:** IIT2015-18-Mita-MK3475

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US State:** CA

**Contact:** Parisa Mirzadehgan [310-967-4387; Parisa.Mirzadehgan@cshs.org]

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Breast Cancer, Ovarian Cancer

**Variant class:** BRCA mutation

**Other inclusion criteria:** ERBB2 negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

## BRCA2 truncating mutation (continued)

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

## BRCA2 truncating mutation (continued)

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIR017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## BRCA2 truncating mutation (continued)

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

**BRCA2 truncating mutation (continued)****NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]



## BRCA2 deletion

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** BRCA2 deletion

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA2 deletion (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 deletion (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** BRCA2 deletion

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## BRCA2 deletion (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 deletion

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapies:** hormone therapy, olaparib, steroid

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA2 deletion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** BRCA2 deletion

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

## BRCA2 deletion (continued)

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** BRCA2 deletion

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** BRCA2 deletion

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAparib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** HRR deletion

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## BRCA2 deletion (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair deletion

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA2 deletion (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## BRCA2 fusion

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA2 fusion (continued)

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variant class:** Fanconi anemia pathway

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## BRCA2 fusion (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## BRCA2 fusion (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** BRCA2 fusion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT02502266**

A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women With Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA fusion

**Other identifiers:** 16-715, COCOS, GY005, GY005-, GYN 9814, jRCT2031190097, KCT0004526, N 33516, NCI-2015-00651, NRG OV1405, NRG-GY005, OVC2, OVM1405, S16-01681

**Population segments:** (N/A), BRCA, Fourth line or greater, Second line, Third line

**Phase:** II/III

**Therapies:** cediranib, olaparib

**Locations:** Japan, United States

**US State:** SD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04739800**

A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor (Durvalumab) MEDI4736 in Combination With Olaparib and Cediranib) Compared to Olaparib and Cediranib or (Durvalumab) MEDI4736 and Cediranib or Standard of Care Chemotherapy in Women With Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab

**Cancer type:** Ovarian Cancer

**Variant class:** BRCA fusion

**Other identifiers:** NCI-2021-00615, NRG-GY023

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** durvalumab, olaparib, cediranib

**Location:** United States

**US States:** CA, GA, IA, ID, IL, MD, ME, MN, MO, MT, NC, NE, NV, NY, OH, OK, OR, PA, RI, TN, TX, WA, WI, WV

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 fusion (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA2 fusion (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## BRCA2 aberration

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** olaparib

**Location:** Canada

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** BRCA2 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## BRCA2 aberration (continued)

**NCT02286687**

Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

**Cancer type:** Unspecified Cancer

**Variation class:** Fanconi anemia pathway

**Other identifiers:** 2013-0961, NCI-2014-02494

**Population segments:** Fourth line or greater, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variation class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variation class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## BRCA2 aberration (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## BRCA2 aberration (continued)

**NCT04666740**

A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

**Cancer type:** Pancreatic Cancer

**Variant class:** BRCA2 aberration

**Other identifier:** 20-481

**Population segments:** BRCA, Maintenance/Consolidation, Stage IV

**Phase:** II

**Therapies:** pembrolizumab, olaparib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Wungki Park [646-888-4543; yaqubiea@mskcc.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## BRCA2 aberration (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>BRCA2 mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<b>BRCA2 splice site mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<b>BRCA2 truncating mutation</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>bevacizumab + olaparib</b> <sup>1,2</sup> <b>niraparib</b> <sup>1</sup> <b>olaparib</b> <sup>1,2</sup> <b>rucaparib</b> <sup>1,2</sup>	78
<b>BRCA2 deletion</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	21
<b>BRCA2 fusion</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	16
<b>BRCA2 aberration</b>  <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO



## Relevant Therapy Summary

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 × No evidence

### BRCA2 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	● (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	×
niraparib	○	○	×	○	○ (III)
olaparib, pembrolizumab	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
talazoparib, chemotherapy	×	×	×	×	● (II)
atezolizumab	×	×	×	×	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	×	×	×	×	● (II)
ATRN-119	×	×	×	×	● (I/II)
RP-3500, talazoparib	×	×	×	×	● (I/II)
BAY-1895344, niraparib	×	×	×	×	● (I)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
HWH-340	×	×	×	×	● (I)
olaparib, adavosertib	×	×	×	×	● (I)
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
atezolizumab, chemotherapy, niraparib	×	×	×	×	○ (III)
cediranib, olaparib	×	×	×	×	○ (III)
rucaparib, hormone therapy	×	×	×	×	○ (III)
talazoparib, hormone therapy	×	×	×	×	○ (III)
ceralasertib, olaparib	×	×	×	×	○ (II)
durvalumab, olaparib	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
durvalumab, tremelimumab, olaparib	×	×	×	×	○ (II)
hormone therapy, olaparib, steroid	×	×	×	×	○ (II)
niraparib, dostarlimab	×	×	×	×	○ (II)
nivolumab, chemotherapy, hormone therapy	×	×	×	×	○ (II)
nivolumab, ipilimumab	×	×	×	×	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### BRCA2 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
talazoparib, avelumab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA2 splice site mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	ⓘ (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	✕
niraparib	○	○	✕	○	○ (III)
olaparib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
talazoparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
atezolizumab	✕	✕	✕	✕	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ① In this cancer type and other cancer types    
 ✕ No evidence

### BRCA2 splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
olaparib, adavosertib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
atezolizumab, chemotherapy, niraparib	✕	✕	✕	✕	○ (III)
cediranib, olaparib	✕	✕	✕	✕	○ (III)
rucaparib, hormone therapy	✕	✕	✕	✕	○ (III)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
ceralasertib, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, ipilimumab	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type   
 ○ In other cancer type   
 ● In this cancer type and other cancer types   
 × No evidence

### BRCA2 splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, avelumab	×	×	×	×	○ (I/II)
BAY-1895344, pembrolizumab	×	×	×	×	○ (I)
pidnarulex	×	×	×	×	○ (I)
RP12146	×	×	×	×	○ (I)

### BRCA2 truncating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	○	○	● (II)
rucaparib	○	○	○	○	● (II)
bevacizumab + olaparib	○	○	○	○	×
niraparib	○	○	×	○	○ (III)
olaparib, pembrolizumab	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
talazoparib, chemotherapy	×	×	×	×	● (II)
atezolizumab	×	×	×	×	● (II)
olaparib, talazoparib, atezolizumab + talazoparib	×	×	×	×	● (II)
ATRN-119	×	×	×	×	● (I/II)
RP-3500, talazoparib	×	×	×	×	● (I/II)
BAY-1895344, niraparib	×	×	×	×	● (I)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
HWH-340	×	×	×	×	● (I)
olaparib, adavosertib	×	×	×	×	● (I)
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
atezolizumab, chemotherapy, niraparib	×	×	×	×	○ (III)
cediranib, olaparib	×	×	×	×	○ (III)
rucaparib, hormone therapy	×	×	×	×	○ (III)
talazoparib, hormone therapy	×	×	×	×	○ (III)
ceralasertib, olaparib	×	×	×	×	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### BRCA2 truncating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, ipilimumab	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, atezolizumab	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
senaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
olaparib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I/II)
rucaparib, nivolumab, ipilimumab	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
talazoparib, avelumab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA2 deletion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### BRCA2 deletion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy, olaparib, steroid	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

### BRCA2 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
olaparib	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
cediranib, olaparib	✕	✕	✕	✕	○ (II/III)
durvalumab, olaparib, cediranib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

☒ In this cancer type    
 ☐ In other cancer type    
 ☒ In this cancer type and other cancer types    
 ✕ No evidence

### BRCA2 aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	① (II)
olaparib	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab, olaparib	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>BRCA2 mutation</b>  Prognostic significance: None Diagnostic significance: None	None	bevacizumab + olaparib <sup>1,2</sup> niraparib <sup>1</sup> olaparib <sup>1,2</sup> rucaparib <sup>1,2</sup>	78
<b>BRCA2 splice site mutation</b>  Prognostic significance: None Diagnostic significance: None	None	bevacizumab + olaparib <sup>1,2</sup> niraparib <sup>1</sup> olaparib <sup>1,2</sup> rucaparib <sup>1,2</sup>	78
<b>BRCA2 truncating mutation</b>  Prognostic significance: None Diagnostic significance: None	None	bevacizumab + olaparib <sup>1,2</sup> niraparib <sup>1</sup> olaparib <sup>1,2</sup> rucaparib <sup>1,2</sup>	78
<b>BRCA2 deletion</b>  Prognostic significance: None Diagnostic significance: None	None	None	21

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>BRCA2 fusion</i> Prognostic significance: None Diagnostic significance: None	None	None	16
<i>BRCA2 aberration</i> Prognostic significance: None Diagnostic significance: None	None	None	13

Public data sources included in relevant therapies: FDA1, NCCN, EMA2, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### BRCA2 mutation + BRCA2 splice site mutation + BRCA2 truncating mutation + BRCA2 deletion

NCT ID	Title	Phase
NCT04126070	A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors	II

### BRCA2 mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II



## Clinical Trials Summary (continued)

### BRCA2 mutation (continued)

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II

## Clinical Trials Summary (continued)

### BRCA2 mutation (continued)

NCT ID	Title	Phase
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II
NCT04717154	Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II

## Clinical Trials Summary (continued)

### BRCA2 mutation (continued)

NCT ID	Title	Phase
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I

## Clinical Trials Summary (continued)

### BRCA2 mutation (continued)

NCT ID	Title	Phase
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### BRCA2 splice site mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II

## Clinical Trials Summary (continued)

### BRCA2 splice site mutation (continued)

NCT ID	Title	Phase
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II

## Clinical Trials Summary (continued)

### BRCA2 splice site mutation (continued)

NCT ID	Title	Phase
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II
NCT04717154	Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II



## Clinical Trials Summary (continued)

### BRCA2 splice site mutation (continued)

NCT ID	Title	Phase
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLAparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II

## Clinical Trials Summary (continued)

### BRCA2 splice site mutation (continued)

NCT ID	Title	Phase
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I



## Clinical Trials Summary (continued)

### BRCA2 splice site mutation (continued)

NCT ID	Title	Phase
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### BRCA2 truncating mutation

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04171700	A Phase II Multicenter, Open-label Study of Rucaparib as Treatment for Solid Tumors Associated With Deleterious Mutations in Homologous Recombination Repair Genes	II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT04197713	Phase I Sequential Trial of Agents Against DNA Repair (STAR)	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRM) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II

## Clinical Trials Summary (continued)

### BRCA2 truncating mutation (continued)

NCT ID	Title	Phase
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT02975934	TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency	III
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03012321	BRCAaway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
No NCT ID	Phase II Study To Evaluate The Efficacy And Safety Of Niraparib In Recurrent Or Persistent Rare Gynecologic Malignancies With Homologous Recombination Deficiency (JGOG2052)	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03601923	Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04493060	Phase II Study of Niraparib and TSR-042 in Patients With Germline or Somatic BRCA1/2 and PALB2-Related Pancreatic Cancer	II
NCT04717154	Phase II INSPIRE Trial: Ipilimumab With Nivolumab In Molecular-Selected Patients With Castration-Resistant Prostate Cancer.	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II

## Clinical Trials Summary (continued)

### BRCA2 truncating mutation (continued)

NCT ID	Title	Phase
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04858334	APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation	II
NCT02849496	A Phase II Open-Label, Randomized Study of PARP Inhibition (Olaparib) Either Alone or in Combination With Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-Positive Breast Cancer.	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT04261465	The NUVOLA TRIAL: Neoadjuvant Chemotherapy in Unresectable Ovarian Cancer With OLaparib and Weekly Carboplatin Plus Paclitaxel: A Phase II Open-label Multicentre Study	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04089189	A Phase II Study to Evaluate the Efficacy, Safety, and Tolerability of IMP4297 Capsules in Subjects With Germline and/or Systemic BRCA1/2 Mutation Positive Advanced Ovarian Cancer With at Least 2 Prior Lines of Standard Systemic Therapy	II
NCT03990896	Evaluation of Talazoparib, a PARP Inhibitor, in Patients With Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03685331	Harnessing Olaparib, Palbociclib and Endocrine Therapy: A Phase I/II Trial of Olaparib, Palbociclib and Fulvestrant in Patients With BRCA Mutation-associated, Hormone Receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer (HOPE)	I/II
No NCT ID	An Open-Label, Randomised, Phase I/II Trial Of Rucaparib Combined With Nivolumab + or - Ipilimumab To Augment Response In Homologous Repair Deficient Patients With Relapsed Ovarian, Primary Peritoneal And Fallopian Tube Cancer	I/II
NCT03964532	TALAVE: A Pilot Trial of Induction Talazoparib Followed by Combination of Talazoparib and Avelumab in Advanced Breast Cancer	I/II

## Clinical Trials Summary (continued)

### BRCA2 truncating mutation (continued)

NCT ID	Title	Phase
NCT04673448	Phase IB Trial of Niraparib and TSR-042 in Patients With BRCA-Mutated Breast, Pancreas or Ovary Cancer	I
NCT04598321	BrUOG 390: Neoadjuvant Treatment With Talazoparib for Women With Newly Diagnosed, Advanced Ovarian Cancer Associated With a Mutation in BRCA1 or BRCA2 (mBRCA)	I
NCT03598270	A Phase III Randomized, Double-blinded Trial of Platinum-based Chemotherapy With or Without Atezolizumab Followed by Niraparib Maintenance With or Without Atezolizumab in Patients With Recurrent Ovarian, Tubal or Peritoneal Cancer and Platinum Treatment-free Interval (TFIp) >6 Months	III
NCT03278717	International Phase III Randomised Study to Evaluate the Efficacy of Maintenance Therapy With Olaparib and Cediranib or Olaparib Alone in Patients With Relapsed Ovarian Cancer Following a Response to Platinum-based Chemotherapy	III
NCT04915755	A Randomized Phase III Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)	III
NCT03462342	Combination ATR and PARP Inhibitor (CAPRI) Trial With AZD 6738 and Olaparib in Recurrent Ovarian Cancer	II
No NCT ID	An Investigator-Initiated Phase II Trial Of Niraparib For Patients With BRCA-Mutated Unresectable / Recurrent Biliary Tract, Pancreatic And Other Gastrointestinal Cancer (NIR-B)	II
NCT04716686	Niraparib Monotherapy as Maintain and Recurrent Treatment of Endometrial Serous Carcinoma: A Multi-center, Open-label, Prospective Clinical Study	II
NCT04348045	MAZEPPA: Phase II PRODIGE-GERCOR Study to Evaluate MAintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	II
NCT03025035	Open Label, Phase II Pilot Study of Immune Checkpoint Inhibition With Pembrolizumab in Combination With PARP Inhibition With Olaparib in Advanced BRCA-mutated or HDR-defect Breast Cancers	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAParib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

## Clinical Trials Summary (continued)

### BRCA2 truncating mutation (continued)

NCT ID	Title	Phase
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### BRCA2 deletion

NCT ID	Title	Phase
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03012321	BRCAaway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II

## Clinical Trials Summary (continued)

### BRCA2 deletion (continued)

NCT ID	Title	Phase
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPARIB (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### BRCA2 fusion

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I



## Clinical Trials Summary (continued)

### BRCA2 fusion (continued)

NCT ID	Title	Phase
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT02502266	A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women With Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)	II/III
NCT04739800	A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor (Durvalumab) MEDI4736 in Combination With Olaparib and Cediranib) Compared to Olaparib and Cediranib or (Durvalumab) MEDI4736 and Cediranib or Standard of Care Chemotherapy in Women With Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab	II
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLAPARIB (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### BRCA2 aberration

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT02286687	Phase II Study of the PARP Inhibitor Talazoparib in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)	II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I

## Clinical Trials Summary (continued)

### BRCA2 aberration (continued)

NCT ID	Title	Phase
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04666740	A Phase II Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients With Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I



## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

6 Relevant Biomarkers  
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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>CDK12 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 splice site mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 truncating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 deletion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	19
<i>CDK12 fusion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	11
<i>CDK12 aberration</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](http://www.fda.gov).

### CDK12 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** CDK12 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## CDK12 splice site mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** CDK12 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## CDK12 truncating mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** CDK12 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### CDK12 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### CDK12 splice site mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## CDK12 truncating mutation

### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

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### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CDK12 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

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## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### CDK12 mutation + CDK12 splice site mutation + CDK12 truncating mutation + CDK12 deletion

#### NCT04276376

A Multicenter, Open Label, Phase II Basket Trial Exploring the Efficacy And Safety of The Combination of Rucaparib (PARP Inhibitor) And Atezolizumab (Anti-PD-L1 Antibody) In Patients With DNA Repair-Deficient or Platinum-Sensitive Solid Tumors

**Cancer type:** Bladder Urothelial Carcinoma, Non-Small Cell Lung Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant classes:** CDK12 deletion & CDK12 mutation

**Other identifiers:** 2018/2727, ARIANES, EudraCT Number: 2018-001744-62

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ATM deletion (Breast Cancer, Ovarian Cancer), ATM mutation (Breast Cancer, Ovarian Cancer), BARD1 deletion (Breast Cancer, Ovarian Cancer), BARD1 mutation (Breast Cancer, Ovarian Cancer), BRCA1 germline deletion (Breast Cancer, Ovarian Cancer), BRCA1 germline mutation (Breast Cancer, Ovarian Cancer), BRCA2 germline deletion (Breast Cancer, Ovarian Cancer), BRCA2 germline mutation (Breast Cancer, Ovarian Cancer), BRIP1 deletion (Breast Cancer, Ovarian Cancer), BRIP1 mutation (Breast Cancer, Ovarian Cancer), CDK12 deletion (Breast Cancer, Ovarian Cancer), CDK12 mutation (Breast Cancer, Ovarian Cancer), CHEK2 deletion (Breast Cancer, Ovarian Cancer), CHEK2 mutation (Breast Cancer, Ovarian Cancer), FANCA deletion (Breast Cancer, Ovarian Cancer), FANCA mutation (Breast Cancer, Ovarian Cancer), NBN deletion (Breast Cancer, Ovarian Cancer), NBN mutation (Breast Cancer, Ovarian Cancer), PALB2 deletion (Breast Cancer, Ovarian Cancer), PALB2 mutation (Breast Cancer, Ovarian Cancer), RAD51 deletion (Breast Cancer, Ovarian Cancer), RAD51 mutation (Breast Cancer, Ovarian Cancer), RAD51C deletion (Breast Cancer, Ovarian Cancer), RAD51C mutation (Breast Cancer, Ovarian Cancer), RAD51D deletion (Breast Cancer, Ovarian Cancer), RAD51D mutation (Breast Cancer, Ovarian Cancer), RAD54L deletion (Breast Cancer, Ovarian Cancer), RAD54L mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** rucaparib, atezolizumab

**Location:** France

#### NCT04126070

A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors

**Cancer type:** Prostate Cancer

**Variant classes:** DNA repair deletion & DNA repair mutation

**Other identifiers:** 19-384, NCI-2020-02149

**Population segments:** First line, Stage IV

**Phase:** II

**Therapies:** nivolumab, chemotherapy, hormone therapy

**Location:** United States

**US State:** MA

**Contact:** Dr. Xiao X. Wei [617-632-4524; xiaox\_wei@dfci.harvard.edu]

## CDK12 mutation

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium



## CDK12 mutation (continued)

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

## CDK12 mutation (continued)

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

## CDK12 mutation (continued)

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## CDK12 mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CDK12 mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT04751929**

A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifier:** 20-701

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** abemaciclib, atezolizumab

**Location:** United States

**US State:** MA

**Contact:** Dr. Atish Choudhury [617-632-6328; achoudhury@partners.org]

## CDK12 mutation (continued)

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** CDK12 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## CDK12 mutation (continued)

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** CDK12 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## CDK12 mutation (continued)

**NCT04019964**

Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CA209-76M, CRMS-71513, J1933, NCI-2020-03804

**Population segments:** (N/A), Hormone refractory, Second line

**Phase:** II

**Therapy:** nivolumab

**Location:** United States

**US State:** MD

**Contact:** Rana Sullivan [410-614-6337; tomalra@jhmi.edu]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** CDK12 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]



## CDK12 mutation (continued)

**NCT04104893**

A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CHOMP, CSDR-003-18F, NCI-2020-02215

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US States:** CA, FL, IL, MI, NC, NY, WA

**Contact:** Dr. Matthew B. Rettig [310-478-3711; matthew.rettig@va.gov]

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CDK12 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

## CDK12 mutation (continued)

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** HRR mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

## CDK12 mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** HRR mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

## CDK12 mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## CDK12 mutation (continued)

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIR017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** DNA repair mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## CDK12 mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## CDK12 mutation (continued)

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## CDK12 mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]



## CDK12 splice site mutation

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

## CDK12 splice site mutation (continued)

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

## CDK12 splice site mutation (continued)

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfILER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

## CDK12 splice site mutation (continued)

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## CDK12 splice site mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CDK12 splice site mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 splice site mutation or DNA repair splice site mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## CDK12 splice site mutation (continued)

**NCT04751929**

A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifier:** 20-701

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** abemaciclib, atezolizumab

**Location:** United States

**US State:** MA

**Contact:** Dr. Atish Choudhury [617-632-6328; achoudhury@partners.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** CDK12 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## CDK12 splice site mutation (continued)

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** CDK12 mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]



## CDK12 splice site mutation (continued)

**NCT04019964**

Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CA209-76M, CRMS-71513, J1933, NCI-2020-03804

**Population segments:** (N/A), Hormone refractory, Second line

**Phase:** II

**Therapy:** nivolumab

**Location:** United States

**US State:** MD

**Contact:** Rana Sullivan [410-614-6337; tomalra@jhmi.edu]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** CDK12 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

## CDK12 splice site mutation (continued)

**NCT04104893**

A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CHOMP, CSDR-003-18F, NCI-2020-02215

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US States:** CA, FL, IL, MI, NC, NY, WA

**Contact:** Dr. Matthew B. Rettig [310-478-3711; matthew.rettig@va.gov]

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CDK12 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

## CDK12 splice site mutation (continued)

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** HRR mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

## CDK12 splice site mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** HRR mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

## CDK12 splice site mutation (continued)

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## CDK12 splice site mutation (continued)

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIRO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** DNA repair mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

## CDK12 splice site mutation (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## CDK12 splice site mutation (continued)

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China



## CDK12 splice site mutation (continued)

### NCT04095273

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CDK12 truncating mutation

### NCT04550494

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 truncating mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CDK12 truncating mutation (continued)

**NCT02693535**

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** atezolizumab + talazoparib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

**NCT03742895**

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT03967938**

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

## CDK12 truncating mutation (continued)

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** CDK12 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

## CDK12 truncating mutation (continued)

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## CDK12 truncating mutation (continued)

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, M039164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

## CDK12 truncating mutation (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CDK12 truncating mutation (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 truncating mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## CDK12 truncating mutation (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** CDK12 truncating mutation

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04751929**

A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifier:** 20-701

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** abemaciclib, atezolizumab

**Location:** United States

**US State:** MA

**Contact:** Dr. Atish Choudhury [617-632-6328; achoudhury@partners.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** CDK12 mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]



## CDK12 truncating mutation (continued)

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT05011383**

High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** SPLP-003-20F, VA-BAT

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** hormone therapy

**Location:** United States

**US State:** WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; Robert.Montgomery@va.gov]

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

## CDK12 truncating mutation (continued)

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04019964**

Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CA209-76M, CRMS-71513, J1933, NCI-2020-03804

**Population segments:** (N/A), Hormone refractory, Second line

**Phase:** II

**Therapy:** nivolumab

**Location:** United States

**US State:** MD

**Contact:** Rana Sullivan [410-614-6337; tomalra@jhmi.edu]

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

## CDK12 truncating mutation (continued)

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** CDK12 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

**NCT04104893**

A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** CHOMP, CSDR-003-18F, NCI-2020-02215

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US States:** CA, FL, IL, MI, NC, NY, WA

**Contact:** Dr. Matthew B. Rettig [310-478-3711; matthew.rettig@va.gov]

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** CDK12 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

## CDK12 truncating mutation (continued)

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CDK12 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

## CDK12 truncating mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** HRR mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** HRR mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CDK12 truncating mutation (continued)

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## CDK12 truncating mutation (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIRO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

## CDK12 truncating mutation (continued)

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** DNA repair mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## CDK12 truncating mutation (continued)

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## CDK12 truncating mutation (continued)

### NCT04095273

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CDK12 deletion

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

## CDK12 deletion (continued)

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**CDK12 deletion (continued)****NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 deletion

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## CDK12 deletion (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** CDK12 deletion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CDK12 deletion

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

**NCT04104893**

A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CDK12 deletion

**Other identifiers:** CHOMP, CSDR-003-18F, NCI-2020-02215

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US States:** CA, FL, IL, MI, NC, NY, WA

**Contact:** Dr. Matthew B. Rettig [310-478-3711; matthew.rettig@va.gov]

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CDK12 deletion

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

## CDK12 deletion (continued)

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair deletion

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair deletion

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

## CDK12 deletion (continued)

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## CDK12 fusion

### NCT04497116

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

### NCT04901702

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## CDK12 fusion (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## CDK12 fusion (continued)

**NCT03840967**

A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma

**Cancer type:** Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** CDK12 fusion

**Other identifiers:** 20166, 71618, HCRN ESO17-325, NCI-2019-07395

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** FL, IN, MI, NY

**Contact:** Dr. Shadia Jalal [317-274-3658; sjalal@iu.edu]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CDK12 fusion (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## CDK12 aberration

**NCT04497116**

Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CDK12 aberration

**Other identifiers:** 20-521, EudraCT Number: 2020-000301-87, IRAS ID: 286609, NCI-2020-06869, RP-3500-01, TRESR, TRESR Study

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** RP-3500, talazoparib

**Locations:** Canada, Denmark, United Kingdom, United States

**US States:** MA, NC, NY, RI, TN, TX

**Contact:** Dr. Peter Manley [857-322-5553; pmanley@reparerx.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

## CDK12 aberration (continued)

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

## CDK12 aberration (continued)

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CDK12 aberration (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>CDK12 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 splice site mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 truncating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	57
<i>CDK12 deletion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	19
<i>CDK12 fusion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	11
<i>CDK12 aberration</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### CDK12 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	ⓘ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
talazoparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)
atezolizumab	✕	✕	✕	✕	● (II)
atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
abemaciclib, atezolizumab	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CDK12 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### CDK12 splice site mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	● (II)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
abemaciclib, atezolizumab	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CDK12 splice site mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### CDK12 truncating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	● (II)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
atezolizumab + talazoparib	✕	✕	✕	✕	● (II)
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### CDK12 truncating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
abemaciclib, atezolizumab	✕	✕	✕	✕	○ (II)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
hormone therapy	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### CDK12 deletion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	✕	✕	✕	✕	ⓘ (II)
talazoparib, chemotherapy	✕	✕	✕	✕	ⓘ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CDK12 deletion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
rucaparib, atezolizumab	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

### CDK12 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
olaparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
niraparib	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

### CDK12 aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
olaparib	✕	✕	✕	✕	● (II)
RP-3500, talazoparib	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types
 ☒ No evidence

### CDK12 aberration (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, palbociclib, axitinib, crizotinib	×	×	×	×	● (I)
olaparib, pembrolizumab	×	×	×	×	○ (II)
pembrolizumab	×	×	×	×	○ (II)
RP12146	×	×	×	×	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>CDK12 mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	57
<b>CDK12 splice site mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	57
<b>CDK12 truncating mutation</b> Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	57
<b>CDK12 deletion</b> Prognostic significance: None Diagnostic significance: None	None	None	19
<b>CDK12 fusion</b> Prognostic significance: None Diagnostic significance: None	None	None	11
<b>CDK12 aberration</b> Prognostic significance: None Diagnostic significance: None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### CDK12 mutation + CDK12 splice site mutation + CDK12 truncating mutation + CDK12 deletion

NCT ID	Title	Phase
NCT04276376	A Multicenter, Open Label, Phase II Basket Trial Exploring the Efficacy And Safety of The Combination of Rucaparib (PARP Inhibitor) And Atezolizumab (Anti-PD-L1 Antibody) In Patients With DNA Repair-Deficient or Platinum-Sensitive Solid Tumors	II

**Disclaimer:** The data presented here is from a curated knowledgebase of publicly available information, but may not be exhaustive. The data version is 2021.11(003).

## Clinical Trials Summary (continued)

### CDK12 mutation + CDK12 splice site mutation + CDK12 truncating mutation + CDK12 deletion (continued)

NCT ID	Title	Phase
NCT04126070	A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors	II

### CDK12 mutation

NCT ID	Title	Phase
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II

## Clinical Trials Summary (continued)

### CDK12 mutation (continued)

NCT ID	Title	Phase
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04751929	A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer	II
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04019964	Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04104893	A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II

## Clinical Trials Summary (continued)

### CDK12 mutation (continued)

NCT ID	Title	Phase
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II

## Clinical Trials Summary (continued)

### CDK12 mutation (continued)

NCT ID	Title	Phase
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### CDK12 splice site mutation

NCT ID	Title	Phase
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II



## Clinical Trials Summary (continued)

### CDK12 splice site mutation (continued)

NCT ID	Title	Phase
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04751929	A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04019964	Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04104893	A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II

## Clinical Trials Summary (continued)

### CDK12 splice site mutation (continued)

NCT ID	Title	Phase
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II

## Clinical Trials Summary (continued)

### CDK12 splice site mutation (continued)

NCT ID	Title	Phase
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### CDK12 truncating mutation

NCT ID	Title	Phase
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II

## Clinical Trials Summary (continued)

### CDK12 truncating mutation (continued)

NCT ID	Title	Phase
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04751929	A Phase II Multi-Center Trial of Abemaciclib With or Without Atezolizumab in Metastatic Castration Resistant Prostate Cancer	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT05011383	High-dose Testosterone in Men With Metastatic Castration-resistant Prostate Cancer and ATM or CDK12 Deficiency	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04019964	Nivolumab as a Non-Castrating Therapy for MMR-deficient and CDK12- Altered Prostate Cancer With PSA Recurrence After Local Therapy	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT04104893	A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation	II

## Clinical Trials Summary (continued)

### CDK12 truncating mutation (continued)

NCT ID	Title	Phase
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II

## Clinical Trials Summary (continued)

### CDK12 truncating mutation (continued)

NCT ID	Title	Phase
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### CDK12 deletion

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04104893	A Phase II Study Of A Checkpoint Inhibitor In Men With Progressive Metastatic Castrate Resistant Prostate Cancer Characterized By A Mismatch Repair Deficiency Or Biallelic CDK12 Inactivation	II



## Clinical Trials Summary (continued)

### CDK12 deletion (continued)

NCT ID	Title	Phase
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### CDK12 fusion

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

## Clinical Trials Summary (continued)

### CDK12 fusion (continued)

NCT ID	Title	Phase
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

### CDK12 aberration

NCT ID	Title	Phase
NCT04497116	Phase I/IIa Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination With Talazoparib in Advanced Solid Tumors With ATR Inhibitor Sensitizing Mutations (TRESR Study)	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I



## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>CHEK1</i> mutation Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	49
<i>CHEK1</i> truncating mutation Prognostic significance: None Diagnostic significance: None	None	olaparib <sup>1</sup>	49
<i>CHEK1</i> deletion Prognostic significance: None Diagnostic significance: None	None	None	15

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](http://www.fda.gov).

### CHEK1 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** CHEK1 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## CHEK1 truncating mutation

### ○ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer

**Label as of:** 2021-03-11

**Variant class:** CHEK1 mutation

#### Indications and usage:

LYNPARZA® is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

##### Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Breast cancer

- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

##### Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA®.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208558s019s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208558s019s020lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### CHEK1 mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CHEK1 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CHEK1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

### CHEK1 truncating mutation

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CHEK1 mutation

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- Adenocarcinoma; Metastatic (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

#### ☐ olaparib

**Cancer type:** Castration-Resistant Prostate Cancer **Variant class:** CHEK1 mutation

**NCCN Recommendation category:** 2B

**Population segment (Line of therapy):**

- Adenocarcinoma; Visceral Metastases (Subsequent therapy); Useful in certain circumstances

**Reference:** NCCN Guidelines® - NCCN-Prostate Cancer [Version 1.2022]

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### CHEK1 mutation + CHEK1 truncating mutation + CHEK1 deletion

#### NCT04126070

A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors

**Cancer type:** Prostate Cancer

**Variant classes:** DNA repair deletion & DNA repair mutation

**Other identifiers:** 19-384, NCI-2020-02149

**Population segments:** First line, Stage IV

**Phase:** II

**Therapies:** nivolumab, chemotherapy, hormone therapy

**Location:** United States

**US State:** MA

**Contact:** Dr. Xiao X. Wei [617-632-4524; xiaox\_wei@dfci.harvard.edu]

### CHEK1 mutation

#### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## CHEK1 mutation (continued)

**NCT03967938**

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03842228**

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 mutation (continued)

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## CHEK1 mutation (continued)

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom



## CHEK1 mutation (continued)

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 mutation (continued)

### NCT03233204

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04267939

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

### NCT04693468

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## CHEK1 mutation (continued)

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** CHEK1 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## CHEK1 mutation (continued)

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** CHEK1 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** CHEK1 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** CHEK1 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

## CHEK1 mutation (continued)

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** CHEK1 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CHEK1 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

## CHEK1 mutation (continued)

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** HRR mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** HRR mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

## CHEK1 mutation (continued)

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** HRR mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

## CHEK1 mutation (continued)

### NCT02264678

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)]

### NCT04890613

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

### NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland



## CHEK1 mutation (continued)

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, REC3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIR017115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

## CHEK1 mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## CHEK1 mutation (continued)

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## CHEK1 mutation (continued)

**NCT04095273**

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CHEK1 truncating mutation

**NCT04550494**

A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** CHEK1 truncating mutation

**Other identifiers:** 000246, 000264-C, 10000264, 10371, NCI-2020-06906

**Population segments:** BRCA, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage II, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** MD

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 truncating mutation (continued)

### NCT03742895

A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variation class:** CHEK1 mutation

**Other identifiers:** (MK-7339-002 / LYNK-002), 19-139, 194694, 2018-01891, 7339-002, 7339-002-00, EudraCT Number: 2018-003007-19, IRAS ID: 255158, JapicCTI-194694, LYNK002, LYNK-002, MK7339-002, MK-7339-002, MK7339-002-00, NCI-2018-03519, PER-046-18, SNCTP000003157

**Population segments:** BRCA, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Ovarian Cancer)

**Phase:** II

**Therapy:** olaparib

**Locations:** Argentina, Australia, Canada, Colombia, Denmark, France, Guatemala, Ireland, Israel, Italy, Mexico, Peru, Republic of Korea, Romania, Russian Federation, Spain, Switzerland, Turkey, United Kingdom, United States

**US States:** AZ, CA, CO, GA, KY, MA, MD, MI, NE, NJ, NY, SD, UT, WA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

### NCT03967938

Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes

**Cancer type:** Unspecified Solid Tumor

**Variation class:** CHEK1 mutation

**Other identifiers:** 1-2018 BSMO, 1-2018BSMO, EudraCT Number: 2018-002966-37, Precision 2 - Olaparib

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer), BRCA2 germline mutation (Breast Cancer, Pancreatic Cancer, Prostate Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** Belgium

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variation class:** CHEK1 mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 truncating mutation (continued)

**NCT04586335**

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** CHEK1 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

**NCT02029001**

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** ET12-081, EudraCT Number: 2012-004510-34, MOST, ProfiLER

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ATM mutation (Gastric Cancer), BRCA1 germline mutation (Gastric Cancer), BRCA1 mutation (Gastric Cancer), BRCA2 germline mutation (Gastric Cancer), BRCA2 mutation (Gastric Cancer), HRR mutation (Gastric Cancer), PALB2 mutation (Gastric Cancer), RAD51 mutation (Gastric Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** France

**NCT04123366**

A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other identifiers:** 7339-007, EudraCT Number: 2019-001745-40, jRCT2011200025, KEYLYNK-007, MK-7339-007, NCI-2019-08758, PER-029-19

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRCA germline mutation (Breast Cancer, Ovarian Cancer), BRCA mutation (Breast Cancer, Ovarian Cancer)

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Locations:** Argentina, Australia, Canada, Colombia, France, Germany, Guatemala, Israel, Italy, Japan, Latvia, Mexico, Peru, Poland, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Sweden, Turkey, Ukraine, United States

**US States:** AL, AZ, CA, CO, FL, GA, KY, NJ, NY, OH, TX, UT, VA

**Contact:** Toll Free Number [888-577-8839; Trialsites@merck.com]

## CHEK1 truncating mutation (continued)

**NCT02401347**

A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0050, NCI-2015-00036, TBB

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA1 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 germline mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), BRCA2 mutation (Breast Cancer, Triple Negative Breast Cancer, Unspecified Solid Tumor), ERBB2 positive (Breast Cancer)

**Phase:** II

**Therapy:** talazoparib

**Location:** United States

**US State:** CA

**Contact:** Amanda Selin [650-721-6977; aselin@stanford.edu]

**NCT03415659**

A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/ Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA1 mutation negative, BRCA2 germline mutation negative, BRCA2 mutation negative

**Other identifiers:** CTR20171649, HWH340-RFPA 20170821, RFPA 20170821

**Population segments:** BRCA, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** HWH-340

**Location:** China

**NCT03767075**

Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifiers:** (Basket of Baskets) (BoB), EudraCT number: 2017-005108-89, MO39164, NL65937.031.18, VHIO17002

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** atezolizumab

**Locations:** France, Germany, Netherlands, Spain, Sweden, United Kingdom

## CHEK1 truncating mutation (continued)

**NCT04905914**

A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair mutation

**Other identifier:** AR-276-01

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ATRN-119

**Location:** United States

**US State:** MA

**Contact:** Robert Hasson [619-540-6253; rhasson@pacificlinkconsulting.com]

**NCT04901702**

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

**NCT03155620**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## CHEK1 truncating mutation (continued)

**NCT03233204**

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; [clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; [tyap@mdanderson.org](mailto:tyap@mdanderson.org)]

## CHEK1 truncating mutation (continued)

**NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** CHEK1 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT03553004**

Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial

**Cancer type:** Pancreatic Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** IIT-2017-NIRA-PANC, NIRA-PANC, STUDY00141862

**Population segments:** BRCA, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US States:** KS, MO

**Contact:** Clinical Trials Nurse Navigator [913-588-3671; navigation@kumc.edu]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** 1412676, NCI-2019-04365, UCDCC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## CHEK1 truncating mutation (continued)

**NCT04187833**

Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.

**Cancer type:** Melanoma

**Variant class:** CHEK1 mutation

**Other identifiers:** CASE2619, NCI-2020-00416

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** nivolumab, talazoparib

**Location:** United States

**US State:** OH

**Contact:** Dr. Pauline Funchain [866-223-8100; TaussigResearch@ccf.org]

**NCT03375307**

A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** CHEK1 mutation

**Other identifiers:** 10144, 19C0023, NCI-2017-02296, P162941

**Population segments:** BRCA, STK11, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, CO, KY, MD, NY, OK

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT03786796**

Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)

**Cancer type:** Kidney Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** CRMS-70750, J18166, NCI-2019-06309, ORCHID

**Population segments:** Fourth line or greater, Second line, Stage IV, Third line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** MD

**Contact:** Irina Rifkind [410-502-2043; irifkin1@jhmi.edu]

**NCT04515836**

Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma

**Cancer type:** Mesothelioma

**Variant class:** CHEK1 mutation

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US State:** IL

**Contact:** Dr. Hedy L. Kindler [773-702-0360; hkindler@medicine.bsd.uchicago.edu]

## CHEK1 truncating mutation (continued)

**NCT03533946**

A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)

**Cancer type:** Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** HCI111833, NCI-2018-01754, ROAR

**Population segments:** First line, Stage I, Stage II, Stage III

**Phase:** II

**Therapy:** rucaparib

**Location:** United States

**US State:** UT

**Contact:** Jill Broghammer [801-213-6232; jill.broghammer@hci.utah.edu]

**NCT04892693**

Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib

**Cancer type:** Breast Cancer

**Variant class:** CHEK1 mutation

**Other identifier:** H-2009-079-1157

**Population segments:** BRCA, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapy:** talazoparib

**Location:** Republic of Korea

**NCT04740190**

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CHEK1 mutation

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

**NCT04253262**

A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** CHEK1 mutation

**Other identifiers:** BrUOG 360, BrUOG360

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, rucaparib

**Location:** United States

**US State:** RI

**Contact:** BrUOG [401-863-3000; BrUOG@brown.edu]

## CHEK1 truncating mutation (continued)

**NCT03810105**

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** DNA repair truncating mutation

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

**NCT04336943**

Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** HRR mutation

**Other identifiers:** 10509, NCI-2020-01860, RG1007001

**Population segments:** Line of therapy N/A, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US State:** WA

**Contact:** Michael Schweizer [206-606-6252; schweize@uw.edu]

**NCT04169841**

Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Head and Neck Cancer, Kidney Cancer, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer

**Variant class:** HRR mutation

**Other identifier:** GUIDE2REPAIR

**Population segments:** Fourth line or greater, Hormone refractory, Maintenance/Consolidation, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Lung Cancer), BRAF mutation (Lung Cancer), EGFR mutation (Lung Cancer), ROS1 mutation (Lung Cancer)

**Phase:** II

**Therapies:** durvalumab, tremelimumab, olaparib

**Location:** France

## CHEK1 truncating mutation (continued)

**NCT03925350**

A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration

**Cancer type:** Melanoma

**Variant class:** HRR mutation

**Other identifier:** CPMC17-MEL01

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Laurel Brechtel [415-600-1654; BrechtLA@sutterhealth.org]

**NCT04940637**

A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes

**Cancer type:** Mesothelioma, Non-Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** ALK fusion negative, CD274 expression, EGFRi sensitizing mutation negative, ROS1 fusion negative or CD274 expression

**Other identifiers:** EudraCT Number: 2020-000109-10, UNITO-001, UNITO-001/2020

**Population segments:** Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** niraparib, dostarlimab

**Location:** Italy

**NCT04042831**

A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations

**Cancer type:** Biliary Tract Carcinoma

**Variant class:** HRR mutation

**Other identifiers:** ACCRU-ICRN-1702, NCI-2019-04434

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AZ, MN, NY, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 truncating mutation (continued)

**NCT04939662**

Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive

**Cancer type:** Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** SUKSES-B2

**Population segments:** (N/A), BRCA, Pulmonary, Second line, Third line

**Phase:** II

**Therapies:** olaparib, bevacizumab

**Location:** Republic of Korea

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** HRR mutation

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT02264678**

A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** HRR mutation

**Other inclusion criteria:** BRCA germline mutation negative, BRCA mutation negative

**Other identifiers:** OC-14-9, 16-031, 18-342, D5330C00004, EudraCT Number: 2014-002233-66, IRAS ID 160200, NCI-2015-00687, Study 4

**Population segments:** Adenocarcinoma, BRCA, HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapies:** ceralasertib, olaparib

**Locations:** France, Republic of Korea, United Kingdom, United States

**US States:** CA, MA, NY

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

**NCT04890613**

Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation

**Cancer type:** Ovarian Cancer

**Variant class:** HRR mutation

**Other identifier:** CX-5461-04

**Population segments:** BRCA, Second line, Stage II, Stage III, Stage IV

**Phase:** I

**Therapy:** pidnarulex

**Location:** Canada

## CHEK1 truncating mutation (continued)

**NCT05002868**

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** HRR mutation

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

**NCT03395197**

A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** BASIC-ROYAL / HIGH-ROYAL, C3441021, CSET 2938, CTR20191443, CTR20191444, EudraCT Number: 2017-003295-31, GU 170 - C3441021, HCC 19-054, JapicCTI-194665, LH19.022, MOH\_2019-05-16\_007127, NCI-2018-01651, Pfizer C3441021, R19062M, RECF3951, RWF\_C3441021 TALAPRO-2, TALAPRO-2, TX228665, UCI-18-47, VICCUIRO17115

**Population segments:** First line, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Czech Republic, Finland, France, Germany, Hungary, Israel, Italy, Japan, New Zealand, Norway, Peru, Poland, Portugal, Republic of Korea, South Africa, Spain, Sweden, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, IN, KS, MO, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]

**NCT04821622**

TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer

**Cancer type:** Prostate Adenocarcinoma

**Variant class:** DNA repair mutation

**Other identifiers:** C3441052, CTR20212191, EudraCT Number: 2021-000248-23, jRCT2031210098, TALAPRO-3

**Population segments:** Second line, Stage IV

**Phase:** III

**Therapies:** talazoparib, hormone therapy

**Locations:** Japan, Republic of Korea, United States

**US States:** CA, DC, FL, GA, IL, MI, NJ, NY, PA, SC, TX, UT

**Contact:** Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov\_Inquiries@pfizer.com]



## CHEK1 truncating mutation (continued)

**NCT03012321**

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU\_16U05, PCCTC #: c16-168, PCCTC c16-168, STU00203960

**Population segments:** First line, Hormone refractory, Stage IV

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** CA, FL, IL, IN, MD, MI, MN, MO, NC, NY, UT, VA

**Contact:** Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

**NCT03344965**

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

**NCT04038502**

An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 01781, 01783, 19-08, BRACeD, CX001963-01, ONCA-009-18F

**Population segments:** First line, Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapies:** olaparib, chemotherapy

**Location:** United States

**US States:** CA, DC, FL, IL, MI, NC, NY, PA, WA

**Contact:** Dr. Robert B. Montgomery [206-277-6878; rbmontgo@u.washington.edu]

## CHEK1 truncating mutation (continued)

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair mutation

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**No NCT ID - see other identifier(s)**

Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** DNA repair mutation

**Other identifier:** ChiCTR1900023234

**Population segments:** Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFRi sensitizing mutation (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** sintilimab

**Location:** China

## CHEK1 truncating mutation (continued)

### NCT04095273

A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors

**Cancer type:** Breast Cancer, Castration-Resistant Prostate Cancer, Colorectal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer

**Variant class:** DNA repair mutation

**Other inclusion criteria:** ATM mutation negative or ATM mutation negative, ERBB2 negative, Hormone receptor positive or ATM underexpression

**Other identifiers:** 19741, EudraCT Number: 2018-003420-36, Keynote 919, NCI-2019-06734

**Population segments:** HER2 negative, Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** BAY-1895344, pembrolizumab

**Locations:** Germany, Spain, Switzerland, United States

**US States:** CA, CT, MA, MD, NC, NY, OH, TX

**Contact:** Bayer Clinical Trials Contact [clinical-trials-contact@bayer.com]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CHEK1 deletion

### NCT04901702

A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma

**Cancer type:** Unspecified Solid Tumor

**Variant class:** HRR pathway

**Other identifiers:** EudraCT Number: 2021-003570-31, ONITT

**Population segments:** Second line, Stage IV

**Exclusion criteria variant classes:** HRR germline pathway (Central Nervous System Neoplasm, Ewing Sarcoma), HRR pathway (Central Nervous System Neoplasm, Ewing Sarcoma)

**Phase:** I/II

**Therapies:** talazoparib, chemotherapy

**Locations:** Canada, United States

**US State:** TN

**Contact:** Dr. Sara Federico [866-278-5833; referralinfo@stjude.org]

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03233204

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 20170841, APEC1621H, NCI-2017-00766

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** olaparib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## CHEK1 deletion (continued)

**NCT04267939**

An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer

**Cancer type:** Ovarian Cancer, Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 18595, 19-810, 2019-0471, 20-222, EudraCT Number: 2018-003930-34, NCI-2020-01405

**Population segments:** Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** DNA repair pathway (Prostate Cancer)

**Phase:** I

**Therapies:** BAY-1895344, niraparib

**Location:** United States

**US States:** MA, NY, TX

**Contact:** Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

**NCT04693468**

Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** DNA repair pathway

**Other identifiers:** 2020-0436, NCI-2020-06041, TalaCom

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** talazoparib, palbociclib, axitinib, crizotinib

**Location:** United States

**US State:** TX

**Contact:** Timothy A. Yap [713-563-1784; tyap@mdanderson.org]

**NCT04030559**

Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects

**Cancer type:** Prostate Cancer

**Variant class:** CHEK1 deletion

**Other identifiers:** 1412676, NCI-2019-04365, UCDC#279

**Population segments:** First line, Neoadjuvant, Stage I, Stage II, Stage IV

**Phase:** II

**Therapy:** niraparib

**Location:** United States

**US State:** CA

**Contact:** Marc Dall'Era [916-734-3771; mdallera@ucdavis.edu]

## CHEK1 deletion (continued)

### NCT04740190

Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** CHEK1 deletion

**Other identifiers:** TAC-GReD, UW-20396

**Population segments:** (N/A), BRCA, Second line

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** Hong Kong

### NCT03810105

A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**Cancer type:** Prostate Cancer

**Variant class:** DNA repair deletion

**Other identifiers:** 18-480, NCI-2019-01627

**Population segments:** Adjuvant, Stage I, Stage II, Stage III

**Phase:** II

**Therapies:** durvalumab, olaparib

**Location:** United States

**US States:** CA, IL, MI, NJ, NY

**Contact:** Dr. Karen Autio [646-422-4632; autiok@mskcc.org]

### NCT03344965

A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

**Cancer type:** Breast Cancer

**Variant class:** DNA repair deletion

**Other inclusion criteria:** BRCA1 germline mutation negative, BRCA2 germline mutation negative

**Other identifiers:** 17-428, 18-414, NCI-2018-00778, TBCRC 048, TBCRC048

**Population segments:** BRCA, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV

**Exclusion criteria variant classes:** BRCA1 germline mutation (Breast Cancer), BRCA2 germline mutation (Breast Cancer)

**Phase:** II

**Therapy:** olaparib

**Location:** United States

**US States:** AL, CA, IL, MA, MD, NC, NJ, NY, PA, WA

**Contact:** Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

## CHEK1 deletion (continued)

**NCT04633902**

Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation

**Cancer type:** Melanoma

**Variant class:** HRR pathway

**Other identifier:** CPMC19-MEL01

**Population segments:** BRAF, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** olaparib, pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Dr. Kevin B. Kim [415-885-8600; ClinicalResearch@sutterhealth.org]

**NCT03248570**

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair deletion

**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408

**Population segments:** BRCA, Hormone refractory, Line of therapy N/A, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United States

**US State:** CA

**Contact:** Patricia Li [415-476-5975; GUTrials@ucsf.edu]

**NCT03506997**

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** DNA repair pathway

**Other inclusion criteria:** MMR deficient

**Other identifiers:** CCR4559, EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

**Population segments:** Hormone refractory, Second line, Stage IV

**Phase:** II

**Therapy:** pembrolizumab

**Location:** United Kingdom

**NCT04849364**

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** DNA repair pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** talazoparib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## CHEK1 deletion (continued)

## NCT05002868

A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Endometrial Carcinoma, Gastric Cancer, Ovarian Cancer, Pancreatic Cancer, Prostate Cancer, Small Cell Lung Cancer

**Variant class:** DNA repair pathway

**Other identifier:** RP12146-2101

**Population segments:** Extensive, Pulmonary, Second line, Stage III, Stage IV

**Exclusion criteria variant class:** ERBB2 positive (Breast Cancer)

**Phase:** I

**Therapy:** RP12146

**Location:** Poland

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>CHEK1 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	49
<i>CHEK1 truncating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	49
<i>CHEK1 deletion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	15

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types
 ☒ No evidence

## CHEK1 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	×	×	● (II)
olaparib, pembrolizumab	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
talazoparib, chemotherapy	×	×	×	×	● (II)
atezolizumab	×	×	×	×	● (II)
ATR-119	×	×	×	×	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

**Disclaimer:** The data presented here is from a curated knowledgebase of publicly available information, but may not be exhaustive. The data version is 2021.11(003).



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CHEK1 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

### CHEK1 truncating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	○	○	✕	✕	● (II)
olaparib, pembrolizumab	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CHEK1 truncating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
atezolizumab	✕	✕	✕	✕	● (II)
ATRN-119	✕	✕	✕	✕	● (I/II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
HWH-340	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
talazoparib, hormone therapy	✕	✕	✕	✕	○ (III)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, tremelimumab, olaparib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
niraparib, dostarlimab	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
nivolumab, talazoparib	✕	✕	✕	✕	○ (II)
olaparib, bevacizumab	✕	✕	✕	✕	○ (II)
olaparib, chemotherapy	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
rucaparib	✕	✕	✕	✕	○ (II)
copanlisib, rucaparib	✕	✕	✕	✕	○ (I/II)
sintilimab	✕	✕	✕	✕	○ (I/II)
BAY-1895344, pembrolizumab	✕	✕	✕	✕	○ (I)
ceralasertib, olaparib	✕	✕	✕	✕	○ (I)
pidnarulex	✕	✕	✕	✕	○ (I)
RP12146	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### CHEK1 deletion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
olaparib	✕	✕	✕	✕	● (II)
talazoparib, chemotherapy	✕	✕	✕	✕	● (II)
BAY-1895344, niraparib	✕	✕	✕	✕	● (I)
talazoparib, palbociclib, axitinib, crizotinib	✕	✕	✕	✕	● (I)
durvalumab, olaparib	✕	✕	✕	✕	○ (II)
niraparib	✕	✕	✕	✕	○ (II)
nivolumab, chemotherapy, hormone therapy	✕	✕	✕	✕	○ (II)
olaparib, pembrolizumab	✕	✕	✕	✕	○ (II)
pembrolizumab	✕	✕	✕	✕	○ (II)
RP12146	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>CHEK1 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	49
<i>CHEK1 truncating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	olaparib <sup>1</sup>	49
<i>CHEK1 deletion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	15

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### CHEK1 mutation + CHEK1 truncating mutation + CHEK1 deletion

NCT ID	Title	Phase
NCT04126070	A Phase II Multicohort Study of Nivolumab in Combination With Docetaxel and Androgen Deprivation Therapy in Metastatic Hormone Sensitive Prostate Cancer Patients With DNA Damage Repair Defects or Inflamed Tumors	II

**Disclaimer:** The data presented here is from a curated knowledgebase of publicly available information, but may not be exhaustive. The data version is 2021.11(003).

## Clinical Trials Summary (continued)

### CHEK1 mutation

NCT ID	Title	Phase
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II

## Clinical Trials Summary (continued)

### CHEK1 mutation (continued)

NCT ID	Title	Phase
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
NCT03375307	A Phase II Study of Olaparib (AZD2281) in Patients With Metastatic/Advanced Urothelial Carcinoma With DNA-Repair Defects	II
NCT03786796	Phase II Study of Olaparib in Metastatic Renal Cell Carcinoma Patients Harboring a BAP-1 or Other DNA Repair Gene Mutations (ORCHID)	II
NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

## Clinical Trials Summary (continued)

### CHEK1 mutation (continued)

NCT ID	Title	Phase
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### CHEK1 truncating mutation

NCT ID	Title	Phase
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	II
NCT03742895	A Phase II Study of Olaparib Monotherapy in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II
NCT03967938	Efficacy of Olaparib in Advanced Cancers Occurring in Patients With Germline Mutations or Somatic Tumor Mutations in Homologous Recombination Genes	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I

## Clinical Trials Summary (continued)

### CHEK1 truncating mutation (continued)

NCT ID	Title	Phase
NCT02029001	A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients with Progressive Locally-advanced or Metastatic Solid Tumors.	II
NCT04123366	A Phase II Study of Olaparib in Combination With Pembrolizumab in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) and/or Homologous Recombination Deficiency (HRD)-Positive Advanced Cancer	II
NCT02401347	A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild Type Patients With Advanced Triple Negative Breast Cancer and Homologous Recombination Deficiency or Advanced HER2 Negative Breast Cancer or Other Solid Tumors With a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial	II
NCT03415659	A Phase I, Open-label, Single-center, Single/Multiple-dose, Dose-escalation/Dose-expansion Clinical Study on Tolerance and Pharmacokinetics of HWH340 Tablet in Patients With Advanced Solid Tumors	I
NCT03767075	Basket of Baskets: A Modular, Open-label, Phase II, Multicentre Study To Evaluate Targeted Agents in Molecularly Selected Populations With Advanced Solid Tumours	II
NCT04905914	A Phase I/IIa, Open-Label, Safety, Pharmacokinetic, And Preliminary Efficacy Study Of Oral ATRN-119 In Patients With Advanced Solid Tumors	I/II
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03553004	Niraparib in Metastatic Pancreatic Cancer After Previous Chemotherapy (NIRA-PANC): A Phase II Trial	II
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04187833	Phase II Trial of Nivolumab in Combination with Talazoparib in Patients with Unresectable or Metastatic Melanoma and Mutations in BRCA or BRCA-ness Genes.	II
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NCT04515836	Phase II Trial of Olaparib in Homologous Recombination Deficient (HRD) Malignant Mesothelioma	II
NCT03533946	A Phase II Study of Rucaparib Monotherapy in Nonmetastatic, Hormone-Sensitive Prostate Cancer Demonstrating "BRCAness" Genotype (ROAR)	II



## Clinical Trials Summary (continued)

### CHEK1 truncating mutation (continued)

NCT ID	Title	Phase
NCT04892693	Talazoparib in Advanced Breast Cancer Patients With Homologous Recombinant Deficiency: A Phase II Clinical and Exploratory Biomarker Study of Talazoparib	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT04253262	A Phase Ib/II Study of Copanlisib Combined With Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer	I/II
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT04336943	Durvalumab (MEDI4736) and Olaparib (AZD2281) for Treatment of Biochemically Recurrent Prostate Cancer in Men Predicted to Have a High Neoantigen Load: A Pilot Study	II
NCT04169841	Precision Medicine Phase II Study Evaluating the Efficacy of a Double Immunotherapy by Durvalumab and Tremelimumab Combined With Olaparib in Patients With Solid Cancers and Carriers of Homologous Recombination Repair Genes Mutation in Response or Stable After Olaparib Treatment	II
NCT03925350	A Phase II Study of Niraparib in Patients With Advanced Melanoma With Genetic Homologous Recombination (HR) Mutation / Alteration	II
NCT04940637	A Phase II, Open-Label, Single Arm, Prospective, Multicenter Study of Niraparib Plus Dostarlimab in Patients With Advanced NSCLC and/or MPM, and Positive for PD-L1 Expression and Germline or Somatic Mutations in the HRR Genes	II
NCT04042831	A Phase II Study of Olaparib in Patients With Advanced Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	II
NCT04939662	Phase II, Single-arm Study of Olaparib and Bevacizumab Combination Therapy in Relapsed Small Cell Lung Cancer Subjects With DNA Damage Response and the Repair Pathway Alteration, ATM Deficiency, SLFN11 Positive, or POU2F3 Positive	II
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT02264678	A Modular Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ceralasertib in Combination With Cytotoxic Chemotherapy and/or DNA Damage Repair/Novel Anti-cancer Agents in Patients With Advanced Solid Malignancies	I
NCT04890613	Phase Ib Expansion Study of CX-5461 in Patients With Solid Tumours and BRCA2 and/or PALB2 Mutation	I
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I
NCT03395197	A Phase III, Randomized, Double-blind, Placebo-controlled Study Of Talazoparib With Enzalutamide In Metastatic Castration-resistant Prostate Cancer	III
NCT04821622	TALAPRO-3: A Phase III, Randomized, Double-blind, Study of Talazoparib With Enzalutamide Versus Placebo With Enzalutamide in Men With DDR Gene Mutated Metastatic Castration-sensitive Prostate Cancer	III
NCT03012321	BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II



## Clinical Trials Summary (continued)

### CHEK1 truncating mutation (continued)

NCT ID	Title	Phase
NCT04038502	An Open-label, Multicenter Phase II Study to Compare the Efficacy of Carboplatin as First-line Followed by Second-line Olaparib Versus Olaparib as First-line Followed by Second-line Carboplatin in the Treatment of Patients With Castration Resistant Prostate Cancer Containing Homologous Recombination Deficiency	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II
No NCT ID	Single-arm Exploratory Study for Sintilimab Second-line or Later-line Treatment of Advanced Non-small Cell Lung Cancer with DDR Pathway Gene Mutation	I/II
NCT04095273	A Multicenter, Non-randomized, Open-label Phase Ib Study to Determine the Maximum Tolerated and Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II

### CHEK1 deletion

NCT ID	Title	Phase
NCT04901702	A Randomized Phase I/II Study of Talazoparib or Temozolomide in Combination With Onivyde in Children With Recurrent Solid Malignancies and Ewing Sarcoma	I/II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03233204	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Olaparib in Patients With Tumors Harboring Defects in DNA Damage Repair Genes	II
NCT04267939	An Open-label Phase Ib Study to Determine the Maximum Tolerated and/or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Combination With PARP Inhibitor Niraparib, in Patients With Recurrent Advanced Solid Tumors and Ovarian Cancer	I
NCT04693468	Modular Phase IB Hypothesis-Testing, Biomarker-Driven, Talazoparib Combination Trial (TalaCom)	I
NCT04030559	Phase II Trial of PARP Inhibitor Niraparib for Men With High Risk Prostate Cancer and DNA Damage Response Defects	II
NCT04740190	Combination Talazoparib - Carboplatin for Recurrent High-grade Glioma With DNA Damage Repair Deficiency (DDRd)	II
NCT03810105	A Phase II Study of Olaparib and Durvalumab in Men With Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair	II
NCT03344965	A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)	II
NCT04633902	Phase II Study of Olaparib in Combination With Pembrolizumab in Patients With Advanced Melanoma With Homologous Recombination (HR) Pathway Gene Mutation	II
NCT03248570	Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects	II

## Clinical Trials Summary (continued)

### CHEK1 deletion (continued)

NCT ID	Title	Phase
NCT03506997	PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT05002868	A Multi-center, Open-label, Phase I/Ib Study to Assess the Safety, Pharmacokinetics and Anti-tumor Activity of RP12146, a Poly (ADP-ribose) Polymerase (PARP) Inhibitor, in Patients With Locally Advanced or Metastatic Solid Tumors	I

## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>EGFR A289T mutation</i>	None	afatinib bevacizumab + erlotinib bevacizumab + gefitinib dacomitinib erlotinib erlotinib + ramucirumab gefitinib gefitinib + chemotherapy	90
<b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None			

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2021-10-01. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### EGFR A289T mutation

#### ☐ afatinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

## EGFR A289T mutation (continued)

### ○ bevacizumab + erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ bevacizumab + gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ dacomitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

## EGFR A289T mutation (continued)

### ○ erlotinib + ramucirumab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ gefitinib + carboplatin + pemetrexed

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ bevacizumab + erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Stage IV (First-line therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

## EGFR A289T mutation (continued)

### ○ bevacizumab + gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Stage IV (First-line therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ erlotinib + ramucirumab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Stage IV (First-line therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ gefitinib + carboplatin + pemetrexed

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Advanced (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ afatinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

## EGFR A289T mutation (continued)

### ○ bevacizumab + erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ bevacizumab + gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ dacomitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

## EGFR A289T mutation (continued)

### ○ erlotinib + ramucirumab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):

- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

### ○ gefitinib + carboplatin + pemetrexed

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR activating mutation

ESMO Level of Evidence/Grade of Recommendation: III / A

Population segment (Line of therapy):


- Stage IV (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]



## Alerts Informed By Public Data Sources

### Current FDA Information

 Contraindicated
  Not recommended
  Resistance
  Breakthrough
  Fast Track

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](http://www.fda.gov).

#### EGFR A289T mutation

### osimertinib + quaratusugene ozeplasmid

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

#### Supporting Statement:

The FDA has granted Fast Track Designation to the immunogene therapy, quaratusugene ozeplasmid, in combination with EGFR inhibitor osimertinib for the treatment of non-small cell lung cancer (NSCLC) with EGFR mutations that progressed after treatment with osimertinib alone.

#### Reference:

<https://www.genprex.com/news/genprex-receives-u-s-fda-fast-track-designation-for-gene-therapy-that-targets-lung-cancer/>

### Current NCCN Information

 Contraindicated
  Not recommended
  Resistance
  Breakthrough
  Fast Track

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

#### EGFR A289T mutation

### atezolizumab

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

#### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "subsequent therapy with pembrolizumab, nivolumab, or atezolizumab is not recommended in patients with EGFR mutations or ALK fusions."

**Reference:** NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 6.2021]

### nivolumab

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

#### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "subsequent therapy with pembrolizumab, nivolumab, or atezolizumab is not recommended in patients with EGFR mutations or ALK fusions."

**Reference:** NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 6.2021]

## EGFR A289T mutation (continued)

### pembrolizumab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR mutation

#### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "subsequent therapy with pembrolizumab, nivolumab, or atezolizumab is not recommended in patients with EGFR mutations or ALK fusions."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 6.2021]

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### EGFR A289T mutation

#### NCT04172597

A Phase II Study of Pozitotinib in Patients With EGFR or HER2 Activating Mutations in Advanced Malignancies

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma, Unspecified Solid Tumor

**Variant class:** EGFR A289T mutation

**Other identifiers:** NCI-2020-13871, SPI-POZ-203

**Population segments:** EGFR, Estrogen receptor positive, HER2 negative, HER2 positive, Second line, Stage IV

**Exclusion criteria variant classes:** EGFR A289T mutation (Non-Small Cell Lung Cancer), EGFR A864V mutation (Non-Small Cell Lung Cancer), EGFR E709K mutation (Non-Small Cell Lung Cancer), EGFR E746\_A750del mutation (Non-Small Cell Lung Cancer), EGFR G598V mutation (Non-Small Cell Lung Cancer), EGFR G719 mutation (Non-Small Cell Lung Cancer), EGFR L858R mutation (Non-Small Cell Lung Cancer), EGFR L861Q mutation (Non-Small Cell Lung Cancer), EGFR P596L mutation (Non-Small Cell Lung Cancer), EGFR R108K mutation (Non-Small Cell Lung Cancer), EGFR R222C mutation (Non-Small Cell Lung Cancer), EGFR R831C mutation (Non-Small Cell Lung Cancer), EGFR R831H mutation (Non-Small Cell Lung Cancer), EGFR S768I mutation (Non-Small Cell Lung Cancer), EGFR T790M mutation (Unspecified Solid Tumor), EGFR V742I mutation (Non-Small Cell Lung Cancer), EGFR V769M mutation (Non-Small Cell Lung Cancer), EGFR V774M mutation (Non-Small Cell Lung Cancer), EGFR exon 20 insertion (Non-Small Cell Lung Cancer), EGFR vIII (Non-Small Cell Lung Cancer), ERBB2 D769H mutation (Non-Small Cell Lung Cancer), ERBB2 D769N mutation (Non-Small Cell Lung Cancer), ERBB2 D769Y mutation (Non-Small Cell Lung Cancer), ERBB2 I655V mutation (Non-Small Cell Lung Cancer), ERBB2 I767M mutation (Non-Small Cell Lung Cancer), ERBB2 L755 mutation (Non-Small Cell Lung Cancer), ERBB2 L786V mutation (Non-Small Cell Lung Cancer), ERBB2 L869R mutation (Non-Small Cell Lung Cancer), ERBB2 R678Q mutation (Non-Small Cell Lung Cancer), ERBB2 S310F mutation (Non-Small Cell Lung Cancer), ERBB2 S310Y mutation (Non-Small Cell Lung Cancer), ERBB2 T733I mutation (Non-Small Cell Lung Cancer), ERBB2 T798I mutation (Unspecified Solid Tumor), ERBB2 T798M mutation (Unspecified Solid Tumor), ERBB2 T862I mutation (Non-Small Cell Lung Cancer), ERBB2 V659E mutation (Non-Small Cell Lung Cancer), ERBB2 V697L mutation (Non-Small Cell Lung Cancer), ERBB2 V773M mutation (Non-Small Cell Lung Cancer), ERBB2 V777L mutation (Non-Small Cell Lung Cancer), ERBB2 V777M mutation (Non-Small Cell Lung Cancer), ERBB2 V842I mutation (Non-Small Cell Lung Cancer), ERBB2 amplification (Breast Cancer, Gastric Cancer), ERBB2 exon 20 insertion (Non-Small Cell Lung Cancer), ERBB2 overexpression (Breast Cancer, Gastric Cancer)

**Phase:** II

**Therapy:** pozitotinib

**Location:** United States

**US State:** CA

**Contact:** Dr. Lyndah Dreiling [949-788-6700; [lyndah.dreiling@sppirx.com](mailto:lyndah.dreiling@sppirx.com)]

## EGFR A289T mutation (continued)

### NCT02465060

Molecular Analysis for Therapy Choice (MATCH).

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR activating mutation

**Other identifiers:** 15-188, 15-7002, 16-750, 20150671, 275215-Z1E, AAAP9159, CTMS# 15-2082, CTSU/EAY131, EAY131, ECOG-ACRIN EAY131, MATCH, NCI-2015-00054, NCI-MATCH

**Population segments:** Adenocarcinoma, Aggressive, BRAF, BRCA, Classical, EGFR, FGFR, Fourth line or greater, HER2 positive, HRAS, Indolent, Large Cell, NRAS, Nodular lymphocyte-predominant, Pulmonary, Second line, Squamous Cell, Stage III, Stage IV, Third line, Unspecified

**Exclusion criteria variant class:** EGFR activating mutation (Glioblastoma, Non-Small Cell Lung Cancer, Small Cell Lung Cancer)

**Phase:** II

**Therapy:** afatinib

**Locations:** Guam, Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03810872

An Open Explorative Phase II, Open Label Study of Afatinib in the Treatment of Advanced Cancer Carrying an EGFR, a HER2 or a HER3 Mutation

**Cancer type:** Unspecified Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 1200.264, 1200264, EudraCT Number: 2016-003411-34, Precision 2, Precision 2 - 1200.264, Precision 2 - Afatinib

**Population segments:** EGFR, HER2 positive, Second line, Squamous Cell, Stage III, Stage IV

**Phase:** II

**Therapy:** afatinib

**Location:** Belgium

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** EGFR mutation

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** erlotinib

**Location:** Italy

## EGFR A289T mutation (continued)

**NCT03239015**

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapies:** gefitinib, erlotinib, afatinib

**Location:** China

**NCT03065387**

Phase I Study of the Pan-ERBB Inhibitor Neratinib Given in Combination With Everolimus, Palbociclib, or Trametinib in Advanced Cancer Subjects With EGFR Mutation/Amplification, HER2 Mutation/Amplification, or HER3/4 Mutation or KRAS Mutation

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR mutation

**Other identifiers:** 2016-0430, NCI-2018-01218

**Population segments:** EGFR, HER2 negative, HER2 positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** neratinib, palbociclib, everolimus, trametinib

**Location:** United States

**US State:** TX

**Contact:** Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

**No NCT ID - see other identifier(s)**

Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR mutation

**Other identifiers:** 5209-CPK-1002, CTR20150792

**Population segments:** EGFR, HER2 positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** pirotinib

**Location:** China

**NCT04128085**

A Phase I, Open-label, Multicenter, Dose Escalation and Expansion Study to Evaluate the Tolerance and Pharmacokinetics of TQB3804 in Subjects With Advanced Malignant Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR mutation

**Other identifiers:** CTR20192284, TQB3804-I-01

**Population segments:** EGFR, First line, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** TQB 3804

**Location:** China

## EGFR A289T mutation (continued)

**NCT03841110**

FT500 as Monotherapy and in Combination With Immune Checkpoint Inhibitors in Subjects With Advanced Solid Tumors (Phase I)

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR positive

**Other identifiers:** 2018-0635, FT500-101, NCI-2019-01692

**Population segments:** Aggressive, Classical, EGFR, Extensive, Fourth line or greater, HER2 positive, Indolent, Merkel, Nodular lymphocyte-predominant, Pulmonary, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** FT500, nivolumab, pembrolizumab, atezolizumab

**Location:** United States

**US States:** CA, MN, NJ, TX

**Contact:** Kimberly Musni [858-875-1800; clinical@fatetherapeutics.com]

**NCT04412616**

A Phase I, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Preliminary Evidence of Antitumor Activity of ZZ06 in Adult Patients With Advanced EGFR Positive Solid Tumor Malignancies

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR positive

**Other identifiers:** 8379643, CTR20210099, NCI-2021-00829, ZZ06-2020A

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** ZZ06

**Location:** United States

**US States:** CA, KS, NY

**Contact:** Shiqi Bai [894-364-2700; baishiqi@intelli-crown.com]

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** EGFR aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** erlotinib

**Location:** Canada

## EGFR A289T mutation (continued)

**NCT04429542**

First-in-Human, Phase I/Ib, Open-label, Multicenter Study of Bifunctional EGFR/TGFβ Fusion Protein BCA101 Alone and in Combination With Pembrolizumab in Patients With EGFR-Driven Advanced Solid Tumors

**Cancer type:** Gastric Cancer, Glioblastoma, Head and Neck Cancer, Hepatocellular Carcinoma, Non-Small Cell Lung Cancer, Ovarian Cancer, Pancreatic Cancer, Rectal Cancer, Thyroid Gland Anaplastic Carcinoma, Triple Negative Breast Cancer, Unspecified Solid Tumor, Uveal Melanoma

**Variant class:** EGFR aberration

**Other identifiers:** 20-147, 2020-0153, BCA101X1101, NCI-2020-04796

**Population segments:** Anaplastic, EGFR, Fourth line or greater, HER2 negative, KRAS, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Phase:** I

**Therapy:** BCA101

**Locations:** Canada, United States

**US States:** MA, NY, PA, TX

**Contact:** David Bohr [617-800-0335; info@bicara.com]

**NCT04511533**

Single Arm Study to Evaluate the Safety of Dacomitinib for the First-Line Treatment of Participants in India With Metastatic Non-Small Cell Lung Cancer With Epidermal Growth Factor Receptor (EGFR)-Activating Mutations

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** A7471064, CTRI/2020/07/026825

**Population segments:** ALK, CNS mets, First line, Stage IV

**Phase:** IV

**Therapy:** dacomitinib

**Location:** India

**No NCT ID - see other identifier(s)**

The Continuous Evaluation of EGFR Mutation in EGFR-mutation Positive Lung Cancer Patients During EGFR TKI Treatment.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifier:** UMIN000037232

**Population segments:** EGFR, Line of therapy N/A, N/A

**Phase:** IV

**Therapy:** EGFR tyrosine kinase inhibitor

**Location:** Japan

**NCT03991403**

Study of Atezolizumab in Combination With Carboplatin + Paclitaxel + Bevacizumab vs With Pemetrexed + Cisplatin or Carboplatin With Stage IV Non-Squamous Non-Small Cell Lung Cancer with EGFR (+) or ALK (+)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 2019-03-027, ATLAS Trial, KCT0004043

**Population segments:** ALK, Adenocarcinoma, EGFR, Large Cell, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** atezolizumab, bevacizumab, chemotherapy

**Location:** Republic of Korea

## EGFR A289T mutation (continued)

### NCT03088059

A Pilot Study of Personalized Biomarker-based Treatment Strategy or Immunotherapy in Patients With Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck

**Cancer type:** Head and Neck Cancer

**Variant class:** EGFR activating mutation

**Other inclusion criteria:** CDKN2A underexpression, HRAS wild type, KRAS wild type, NRAS wild type

**Other identifiers:** 1559-HNCG, EORTC HN1559, EORTC-1559-HNCG, EORTC-HNCG-1559, EudraCT Number: 2017-000086-74, IRAS ID 236404, RECF3462, UPSTREAM

**Population segments:** EGFR, HER2 positive, Second line, Stage IV

**Phase:** II

**Therapy:** afatinib

**Locations:** Belgium, France, Italy, United Kingdom

### NCT04147351

A Phase II Study of Atezolizumab in Combination With Bevacizumab, Carboplatin or Cisplatin, and Pemetrexed for EGFR-mutant Metastatic Non-small Cell Lung Cancer Patients After Failure of EGFR Tyrosine Kinase Inhibitors.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifier:** 201908090MIFA

**Population segments:** EGFR, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** EGFR T790M mutation (Non-Small Cell Lung Cancer), EGFR exon 20 insertion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** atezolizumab, bevacizumab, chemotherapy

**Location:** Taiwan

### NCT04811001

A Randomised Non-comparative, Phase II Study Investigating the Best Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR-TKI) Sequence in Advanced or Metastatic Non Small-Cell Lung Cancer (NSCLC) Harboring EGFR Mutations

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other inclusion criteria:** ALK fusion negative, BRAF mutation negative, ERBB2 mutation negative, KRAS mutation negative, MET mutation negative, ROS1 fusion negative

**Other identifier:** CAPLAND

**Population segments:** EGFR, First line, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** dacomitinib, osimertinib

**Location:** Italy



## EGFR A289T mutation (continued)

**NCT04484142**

Phase II, Single-arm, Open-label Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations and Progressed On or After Applicable Targeted Therapy and Platinum Based Chemotherapy (TROPION-Lung05)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 20-602, DS1062-A-U202, EudraCT Number: 2020-002774-27, jRCT2041200097, TROPION-Lung05

**Population segments:** ALK, BRAF, EGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant class:** KRAS mutation (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** datopotamab deruxtecan

**Locations:** France, Hungary, Italy, Japan, Netherlands, Republic of Korea, Spain, Taiwan, United States

**US States:** CA, FL, MA, MD, MI, MO, NJ, NY, OH, TN, TX, VA, WA

**Contact:** (US sites only) Daiichi Sankyo Contact for Clinical Trial Information [908-992-6400; CTRinfo@dsi.com]

**No NCT ID - see other identifier(s)**  
ITAC 2 TRIAL: Intermittent TKI and Chemotherapy for Patients with Advanced Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** EudraCT Number: 2010-023362-44, ITAC, ITAC 2

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Maintenance/Consolidation, Stage III, Stage IV

**Phase:** II

**Therapies:** erlotinib, chemotherapy

**Location:** Slovenia

**NCT03151161**

A Prospective, Multi-center, Open-labeled Phase II Randomized and Comparative Clinical Study of First Line Intermittent and Maintenance of Icotinib in Combination With Pemetrexed/Carboplatin Compared With Icotinib Single Drug in IIIB/IV Non Small Cell Lung Cancer With Epidermal Growth Factor Receptor (EGFR) Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifier:** 201512001

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Maintenance/Consolidation, Stage III, Stage IV

**Phase:** II

**Therapies:** icotinib hydrochloride, chemotherapy

**Location:** China

## EGFR A289T mutation (continued)

### NCT03292133

A Phase II Study of EGF816 and Gefitinib in TKI-naïve EGFR-mutant Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 17-291, NCI-2017-02352

**Population segments:** EGFR, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** II

**Therapies:** nazartinib, gefitinib

**Location:** United States

**US State:** MA

**Contact:** Beth Kennedy [617-724-1223; EAKENNEDY@mgh.harvard.edu]

### NCT04335292

Osimertinib Then Chemotherapy in EGFR-mutated Lung Cancer With Osimertinib Third-line Rechallenge

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other inclusion criteria:** EGFR exon 20 insertion negative

**Other identifier:** OCELOT

**Population segments:** EGFR, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** osimertinib

**Location:** Canada

### NCT04410796

A Phase II Randomized Study of Osimertinib Versus Osimertinib Plus Chemotherapy for Patients With Metastatic EGFR-Mutant Lung Cancers That Have Detectable EGFR-Mutant cfDNA in Plasma After Initiation of Osimertinib

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 20-011, NCI-2020-04069

**Population segments:** EGFR, First line, Second line, Stage IV

**Phase:** II

**Therapies:** osimertinib, chemotherapy

**Location:** United States

**US States:** MD, NJ, NY, TN

**Contact:** Dr. Helena Yu [646-608-2252; yuh@mskcc.org]

## EGFR A289T mutation (continued)

### NCT03318939

A Phase II Study of Pozitotinib in Patients With Non-Small Cell Lung Cancer (NSCLC), Locally Advanced or Metastatic, With EGFR or HER2 Exon 20 Insertion Mutation (ZENITH20).

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 18-059, 19387, 2017-0857, 20172584, EudraCT Number:

2018-001868-36, NCI-2018-00078, NL66741.078.18, POZITIVE20-1, SPECTRUM20, SPI-POZ-202, UCI-17-101, ZENITH20, ZENITH20-1

**Population segments:** EGFR, First line, Fourth line or greater, HER2 positive, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** EGFR C797S mutation (Non-Small Cell Lung Cancer), EGFR G779F mutation (Non-Small Cell Lung Cancer), EGFR G796A mutation (Non-Small Cell Lung Cancer), EGFR T790M mutation (Non-Small Cell Lung Cancer), EGFR V769L mutation (Non-Small Cell Lung Cancer), EGFR V774M mutation (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** pozitotinib

**Locations:** Belgium, Canada, Israel, Italy, Netherlands, United States

**US States:** AZ, CA, CT, DC, FL, GA, IL, MA, MD, MI, MN, NC, NY, OH, TN, TX, VA, WA

**Contact:** Dr. Lyndah Dreiling [949-788-6700; spi-poz-202@sppirx.com]

### NCT04862780

A Phase I/II Study Targeting Acquired Resistance Mechanisms in Patients With EGFR Mutant Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 2021-0267, BLU-945-1101

**Population segments:** Adenocarcinoma, EGFR, Second line, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF V600E mutation (Non-Small Cell Lung Cancer), EGFR exon 20 mutation (Non-Small Cell Lung Cancer), ERBB2 aberration (Non-Small Cell Lung Cancer), KRAS aberration (Non-Small Cell Lung Cancer), MET aberration (Non-Small Cell Lung Cancer), NTRK1 aberration (Non-Small Cell Lung Cancer), NTRK2 aberration (Non-Small Cell Lung Cancer), NTRK3 aberration (Non-Small Cell Lung Cancer), RET aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapy:** BLU-945

**Location:** United States

**US States:** CA, MA, NY, TN, TX

**Contact:** Blueprint Medicines [617-714-6707; medinfo@blueprintmedicines.com]

### No NCT ID - see other identifier(s)

Phase I/II Study of Brigatinib plus Panitumumab in Patients with Advanced EGFR-mutated Non-small Cell Lung Cancer Harboring C797S Resistant Mutation to Osimertinib

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** BEBOP, jRCT2031200231

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** brigatinib, panitumumab

**Location:** Japan

## EGFR A289T mutation (continued)

### NCT02716116

A Phase I/II Study of the Safety, Pharmacokinetics, and Anti-Tumor Activity of the Oral EGFR/HER2 Inhibitor TAK-788 (AP32788) in Non-Small Cell Lung Cancer.

**Cancer type:** Biliary Tract Carcinoma, Bladder Urothelial Carcinoma, Breast Cancer, Esophageal Cancer, Gastric Cancer, Head and Neck Cancer, Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 16-0208, 16-143, 16-447, 2016-1030, AP32788-15-101, EudraCT Number: 2016-001271-68, IRAS ID 257847, JapicCTI-195000, LUN0082, NCI-2016-00587, RECF3968, SHS\_492405 PARM CARI 17177, TAK15101-A15101, Takeda EXCLAIM, U1111-1217-7205, UCI-17-83, VICCTHO1614

**Population segments:** CNS mets, EGFR, First line, Fourth line or greater, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** mobocertinib, chemotherapy

**Location:** United States

**US States:** AZ, CA, FL, GA, NC, VA

**Contact:** Takeda Contact [877-825-3327; medinfoUS@takeda.com]

### NCT04486833

A Phase I/II Open-Label, Dose-escalation and Clinical Response Study of GPX-001 in Combination With Osimertinib in Patients With Advanced, Metastatic EGFR-mutant Non-small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** Acclaim-1, GEN-104

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** quaratusugene ozeplasmid, osimertinib

**Location:** United States

**US State:** TX

**Contact:** VP of Clinical Operations [877-774-4679; sinman@genprex.com]

### No NCT ID - see other identifier(s)

A Phase I Study Afatinib In Combination Of Osimertinib In Patients With Relapsed Non-Small Cell Lung Cancer After Failure of Prior Osimertinib

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** AfaOsi trial, jRCTs051180008, UMIN000031501

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** afatinib, osimertinib

**Location:** Japan

## EGFR A289T mutation (continued)

### NCT03755102

A Pilot Study of Dacomitinib With or Without Osimertinib for Patients With Metastatic EGFR Mutant Lung Cancers With Disease Progression on Osimertinib

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 18-341, NCI-2018-03226

**Population segments:** EGFR, Second line, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), MET amplification (Non-Small Cell Lung Cancer), RET fusion (Non-Small Cell Lung Cancer)

**Phase:** I

**Therapy:** dacomitinib

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. Helen Yu [646-888-4274; YuH@mskcc.org]

### NCT04762199

A Phase Ib Safety and Pharmacodynamic Study of MER Tyrosine Kinase Inhibitor, MRX-2843, in Combination With Osimertinib in Advanced EGFR Mutant Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifiers:** NCI-2020-08392, STUDY00001681, WINSHIP5153-20

**Population segments:** EGFR, Second line, Stage IV

**Phase:** I

**Therapies:** MRX-2843, osimertinib

**Location:** United States

**US State:** GA

**Contact:** Dr. Taofeek Owonikoko [404-778-4576; towonik@emory.edu]

### NCT03891615

Phase I Study of Niraparib in Combination With Osimertinib in EGFR-Mutated Advanced Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 18-613, NCI-2019-03870

**Population segments:** EGFR, Line of therapy N/A, Stage IV

**Phase:** I

**Therapies:** niraparib, osimertinib

**Location:** United States

**US State:** MA

**Contact:** Dr. Zofia Piotrowska [617-643-9707; zofia.piotrowska@mgh.harvard.edu]

## EGFR A289T mutation (continued)

### NCT04250545

A Phase I Trial of MLN0128 (Sapanisertib) and CB-839 HCl (Telaglenastat) in Advanced NSCLC Patients

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** 10327, NCI 10327, NCI-2020-00478, PHI-113

**Population segments:** ALK, Adenocarcinoma, BRAF, EGFR, KRAS, Large Cell, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** telaglenastat, sapanisertib

**Location:** United States

**US States:** CA, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03114319

An Open-label, Multi-center, Phase I, Dose Finding Study of Oral TNO155 in Adult Patients With Advanced Solid Tumors.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other inclusion criteria:** BRAF wild type, RAS wild type

**Other identifiers:** 17-251, 17-266, CTNO155X2101, EudraCT Number: 2016-001861-10, JapicCTI-184236, NCI-2017-01726, NL60195.056.16, TNO155X2101

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** BRAF activating mutation (Unspecified Solid Tumor), HRAS activating mutation (Unspecified Solid Tumor), KRAS activating mutation (Unspecified Solid Tumor), NRAS activating mutation (Unspecified Solid Tumor), PTPN11 activating mutation (Unspecified Solid Tumor)

**Phase:** I

**Therapies:** TNO-155, nazartinib

**Locations:** Canada, Japan, Netherlands, Republic of Korea, Singapore, Spain, Taiwan, United States

**US States:** MA, NY, TN

**Contact:** Novartis Pharmaceuticals [888-669-6682; [trialandresults.registries@novartis.com](mailto:trialandresults.registries@novartis.com)]

## EGFR A289T mutation (continued)

### NCT04197934

Phase I Study to Evaluate Safety, Tolerability, Pharmacokinetics and Anti-Tumor Activity of WSD0922-FUFU

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR activating mutation

**Other identifiers:** MC1914, NCI-2019-07825

**Population segments:** EGFR, First line, Second line, Stage IV

**Exclusion criteria variant classes:** EGFR C797S mutation & EGFR L858R mutation & EGFR T790M mutation (Anaplastic Astrocytoma IDH-wild type, Glioblastoma IDH-wild type, Non-Small Cell Lung Cancer), EGFR C797S mutation & EGFR T790M mutation & EGFR exon 19 deletion (Anaplastic Astrocytoma IDH-wild type, Glioblastoma IDH-wild type, Non-Small Cell Lung Cancer), EGFR L858R mutation & EGFR T790M mutation (Anaplastic Astrocytoma IDH-wild type, Glioblastoma IDH-wild type, Non-Small Cell Lung Cancer), EGFR T790M mutation & EGFR exon 19 deletion (Anaplastic Astrocytoma IDH-wild type, Glioblastoma IDH-wild type, Non-Small Cell Lung Cancer)

**Phase:** I

**Therapy:** WSD-0922

**Location:** United States

**US States:** AZ, FL, MN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04413201

AFAMOSI: Prospective, Randomized, Multicenter Phase IV Study to Evaluate the Efficacy and Safety of Afatinib Followed by Osimertinib Compared to Osimertinib in Patients With EGFRmutated/T790M Mutation Negative Non-squamous NSCLC in the First-line Setting

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifiers:** AFAMOSI, EudraCT Number: 2019-002197-31

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage III, Stage IV

**Exclusion criteria variant class:** EGFR T790M mutation (Non-Small Cell Lung Cancer)

**Phase:** IV

**Therapies:** afatinib, osimertinib

**Location:** Germany

### No NCT ID - see other identifier(s)

Apatinib Combined With EGFR-TKI For Patients With EGFR Mutation Who Failed EGFR-TKI: A Prospective Study

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR1800017863

**Population segments:** EGFR, Second line, Stage IV

**Phase:** IV

**Therapy:** apatinib + EGFR tyrosine kinase inhibitor

**Location:** China

## EGFR A289T mutation (continued)

### No NCT ID - see other identifier(s)

A Real World Study Of Apatinib Combined With Gefitinib In The Treatment Of EGFRm+ Advanced Non-Squamous Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR2000040093

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage III, Stage IV

**Phase:** IV

**Therapies:** apatinib, gefitinib

**Location:** China

### No NCT ID - see other identifier(s)

Clinical Study Of Combined Action Of Gefitinib And Brain Radiotherapy On EGFR-Mutated Non-Small-Cell Lung Cancer Patients With Brain Metastasis

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR-OOC-17012107

**Population segments:** CNS mets, EGFR, Line of therapy N/A, N/A

**Phase:** IV

**Therapies:** gefitinib, radiation therapy

**Location:** China

### No NCT ID - see other identifier(s)

A Multicenter, Open-Label, Single Arm Pilot Study: Osimertinib As Neoadjuvant Treatment For Resectable Stage II-IIIa EGFR Mutant Lung Adenocarcinoma.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** ChiCTR1800016948, NEOS

**Population segments:** Adenocarcinoma, EGFR, Neoadjuvant, Stage II, Stage III

**Exclusion criteria variant class:** EGFR exon 20 insertion (Non-Small Cell Lung Cancer)

**Phase:** IV

**Therapy:** osimertinib

**Location:** China

### NCT03992885

Combination Therapy With Icotinib, Pemetrexed and Platinum in Patients With Metastatic Non-squamous Non-small Cell Lung Cancer With EGFR Mutations Who Did Not Progress After Pemetrexed in Combination With Platinum-based Chemotherapy: a Single-arm, Open, Multicenter Clinical Study.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** E2019161

**Population segments:** Adenocarcinoma, EGFR, Large Cell, Maintenance/Consolidation, Second line, Stage IV

**Phase:** III

**Therapies:** icotinib hydrochloride, chemotherapy

**Location:** China



## EGFR A289T mutation (continued)

**No NCT ID - see other identifier(s)**

A Phase II Study Of Afatinib For Advanced Non-Small Cell Lung Cancer With Uncommon Epidermal Growth Factor Receptor (EGFR) Mutation Including Compound Mutation Detected By Next Generation Sequencing

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** jRCTs041190027

**Population segments:** EGFR, First line, Stage III, Stage IV

**Exclusion criteria variant classes:** EGFR T790M mutation (Non-Small Cell Lung Cancer), EGFR exon 20 insertion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** afatinib

**Location:** Japan

**NCT04785742**

An Open, Multicenter Phase II Clinical Study to Evaluate the Safety and Efficacy of Almonertinib in Patients With Advanced NSCLC With Rare Mutations in EGFR

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR exon 19 deletion negative, EGFR exon 20 insertion negative, EGFR L858R mutation negative

**Other identifier:** YX-L-202008

**Population segments:** EGFR, First line, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** EGFR L858R mutation (Non-Small Cell Lung Cancer), EGFR exon 19 deletion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** almonertinib

**Location:** China

**No NCT ID - see other identifier(s)**

Safety and efficacy analysis of Ametinib combined with Pemetrexed intraoperatively for treatment of EGFR mutant lung cancer with meningeal metastases after first-line TKI failure

**Cancer type:** Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR2100047017

**Population segments:** Adenocarcinoma, CNS mets, EGFR, Second line, Stage IV

**Phase:** II

**Therapies:** almonertinib, chemotherapy

**Location:** China

**No NCT ID - see other identifier(s)**

A Single-center, Open Label, Phase II Study of Anlotinib as Second/Third-line Treatment for Advanced Non-small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifier:** ChiCTR1800017585

**Population segments:** EGFR, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** anlotinib hydrochloride

**Location:** China

## EGFR A289T mutation (continued)

**NCT04619563**

A Single-arm Exploratory Clinical Study of Anlotinib Hydrochloride Combined With Docetaxel in EGFR Mutations Advanced Non Small Cell Lung Cancer Patients Who Have Progressed After Targeted Therapy and Chemotherapy

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** ALK mutation negative

**Other identifier:** SDZLEC2020-052-02

**Population segments:** Adenocarcinoma, EGFR, Large Cell, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** anlotinib hydrochloride, chemotherapy

**Location:** China

**No NCT ID - see other identifier(s)**

Clinical Study And Safety Analysis On The Treatment Of Advanced Non-Small Cell Lung Cancer With Anlotinib And Gefitinib

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR2000030525

**Population segments:** EGFR, Second line, Stage II, Stage III, Stage IV

**Phase:** II

**Therapies:** anlotinib hydrochloride, gefitinib

**Location:** China

**NCT04245085**

A Randomised Non-comparative Open Label Phase II Trial of Atezolizumab Plus Bevacizumab, With Carboplatin-paclitaxel or Pemetrexed, in EGFR-mutant Non-small Cell Lung Carcinoma With Acquired Resistance

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** ABC-lung, EOTP-ABC, ETOP 15-19, ETOP 15-19 ABC-lung, ETOP\_15-19, EudraCT Number: 2019-001687-30, KCT0005588, MO40586, NCC2020-0267

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** atezolizumab, bevacizumab, chemotherapy

**Locations:** Germany, Singapore, Spain, Switzerland

**No NCT ID - see other identifier(s)**

Osimertinib Combined Bevacizumab in Untreated Epidermal Growth Factor Receptor Mutated Non-small-cell Lung Cancer Patients with Malignant Pleural And/Or Pericardial Effusion -phase II Trial

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** SPIRAL II, UMIN000028071

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage IV

**Phase:** II

**Therapies:** bevacizumab, osimertinib

**Location:** Japan

## EGFR A289T mutation (continued)

**No NCT ID - see other identifier(s)**

Randomized Controlled Trial for EGFR-TKIs Plus S-1 or EGFR-TKIs as the First-Line Therapy for Patients with Advanced Non-small Cell Lung Cancer Harboring EGFR Mutations

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR1900020520

**Population segments:** EGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** EGFR tyrosine kinase inhibitor + chemotherapy, EGFR tyrosine kinase inhibitor

**Location:** China

**No NCT ID - see other identifier(s)**

EGFR-TKI Combined With Stereotactic Body Radiation Therapy Versus TKI alone for Stage IV Oncogene-Driven Non-Small Cell Lung Cancer.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR1900027030

**Population segments:** EGFR, Line of therapy N/A, Stage IV

**Phase:** II

**Therapies:** EGFR tyrosine kinase inhibitor, radiation therapy

**Location:** China

**NCT03904823**

An Open, Single-arm, Multi-center, Phase II Clinical Trial of Famitinib Combined With Epidermal Growth Factor Receptor (EGFR) Inhibitor HS-10296 in Patients With Advanced EGFR-mutant Non-Small Cell Lung Cancer (NSCLC)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CTR20190458, CTR20191893, FMTN-II-203-NSCLC

**Population segments:** EGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** famitinib, almonertinib

**Location:** China

**NCT01784549**

A Multi-center Phase II Randomized Study of Customized Neoadjuvant Therapy Versus Standard Chemotherapy in Non-small Cell Lung Cancer (NSLC) Patients With Resectable Stage IIIA (N2) Disease

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CONTEST, CONTEST TRIAL, CONTEST TRIAL RF-2009-1530324, CONTEST-TRIAL, EudraCT Number: 2011-005267-24, RF-2009-1530324

**Population segments:** Adenocarcinoma, EGFR, Large Cell, Neoadjuvant, Other subtype, Squamous Cell, Stage III

**Phase:** II

**Therapy:** gefitinib

**Location:** Italy

## EGFR A289T mutation (continued)

**No NCT ID - see other identifier(s)**

Gefitinib Plus Pemetrexed Combined With Bevacizumab Or Carboplatin In First-Line Treatment Of Stage IV EGFR Mutant Non-Squamous Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR2100043395

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage IV

**Phase:** II

**Therapies:** gefitinib, bevacizumab, chemotherapy

**Location:** China

**No NCT ID - see other identifier(s)**

Open-Label, Single arm, Phase II trial to Evaluate Efficacy and Safety of Nivolumab as Maintenance Therapy Following Platinum-based Chemotherapy in Non-Small Cell Lung Cancer Patients after Tyrosine Kinase Inhibitor Therapy

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** EGFR\_IO, KCT0004541

**Population segments:** ALK, EGFR, Maintenance/Consolidation, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** nivolumab

**Location:** Republic of Korea

**NCT04538378**

Phase II Trial of Olaparib (LYNPARZA) Plus Durvalumab (IMFINZI) in EGFR-Mutated Adenocarcinomas That Transform to Small Cell Lung Cancer (SCLC) and Other Neuroendocrine Tumors.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 200149, 20-C-0149, NCI-20-C-0149

**Population segments:** (N/A), Adenocarcinoma, EGFR, Pulmonary, Second line, Unspecified

**Phase:** II

**Therapies:** olaparib, durvalumab

**Location:** United States

**US State:** MD

**Contact:** Linda C. Sciuto [240-760-6117; lsciuto@mail.nih.gov]

**No NCT ID - see other identifier(s)**

Phase II trial of osimertinib for rare EGFR mutation-positive non-small cell lung cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR exon 19 deletion negative, EGFR exon 20 insertion negative, EGFR L858R mutation negative, EGFR T790M negative

**Other identifiers:** jRCTs071200002, TCOG-LC1901, UNICORN

**Population segments:** Adenocarcinoma, EGFR, First line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), BRAF mutation (Non-Small Cell Lung Cancer), EGFR L858R mutation (Non-Small Cell Lung Cancer), EGFR T790M mutation (Non-Small Cell Lung Cancer), EGFR exon 19 deletion (Non-Small Cell Lung Cancer), EGFR exon 20 insertion (Non-Small Cell Lung Cancer), ROS1 fusion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** osimertinib

**Location:** Japan

## EGFR A289T mutation (continued)

**NCT03460275**

Osimertinib as First-line Therapy for Patients With EGFR Mutation-positive Locally Advanced or Metastatic Non-squamous Non-Small Cell Lung Cancer (NSCLC), a Single-Arm, Open-Label, Prospective, Multicenter, Phase II Clinical Trial

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** A2018-001

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage III, Stage IV

**Exclusion criteria variant class:** EGFR exon 20 insertion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** osimertinib

**Location:** China

**No NCT ID - see other identifier(s)**

Efficacy Of Osimertinib With Platinum And Pemetrexed In EGFR Mutant Non-Small Cell Lung Cancer Patients Bearing CNS Metastasis, And Have Systemic Progression But Stable Intracranial Disease On Osimertinib Resistance. (EPONA)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** (EPONA), jRCTs071200029, TORG1938 (EPONA Study)

**Population segments:** Adenocarcinoma, CNS mets, EGFR, Large Cell, Second line, Stage IV

**Phase:** II

**Therapies:** osimertinib, chemotherapy

**Location:** Japan

**NCT03087071**

A Phase II Enrichment Study of Panitumumab as a Single Agent or in Combination With Trametinib in Anti-EGFR-Refractory Stage IV Colorectal Cancer Patients

**Cancer type:** Colorectal Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 2016-0338, NCI-2017-00868

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** panitumumab

**Location:** United States

**US State:** TX

**Contact:** Christine Parseghian [713-795-9280; cparseghian@mdanderson.org]

**No NCT ID - see other identifier(s)**

An Exploratory Clinical Study Of PD-1 Inhibitor Combined With Chemotherapy In The Treatment Of Advanced Non-small Cell Lung Cancer With EGFR Mutation Positive And T790M Negative After Failure Of TKI Combined With Antiangiogenic Drugs

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifier:** ChiCTR2000039514

**Population segments:** Adenocarcinoma, EGFR, Large Cell, Second line, Squamous Cell, Stage III, Stage IV

**Phase:** II

**Therapies:** PD-1 Inhibitor, chemotherapy

**Location:** China

## EGFR A289T mutation (continued)

**NCT03574402**

An Open-label, Multi-center, Phase II Umbrella Study to Assess Efficacy of Targeted Therapy or Immunotherapy Directed by Next Generation Sequencing (NGS) in Chinese Patients With Advanced NSCLC (TRUMP)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CTONG1702, TRUMP

**Population segments:** ALK, EGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pirotinib

**Location:** China

**No NCT ID - see other identifier(s)**

A Multicenter, Open-label Phase IIb Clinical Study to Evaluate the Efficacy and Safety of SZMD in Patients with Locally Advanced or Metastatic Lung Cancer (Non-resistant Rare EGFR Mutations Only, Including L861Q, G719X and/or S768I)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR2100051136

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** sutetinib

**Location:** China

**No NCT ID - see other identifier(s)**

A Single-Center, Open-Label, Non-Randomized Control Clinical Trial On Clinical Features And Medical Treatment Of Advanced NSCLC With Rare Gene Mutations

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR1800017709

**Population segments:** BRAF, EGFR, KRAS, Second line, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK fusion (Non-Small Cell Lung Cancer), EGFR L858R mutation (Non-Small Cell Lung Cancer), EGFR exon 19 deletion (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapies:** targeted therapy, chemotherapy

**Location:** China

**No NCT ID - see other identifier(s)**

Clinical Study of Combined Action of the First Generation of TKIs and Brain Radiotherapy on EGFR-Mutated Non-Small-Cell Lung Cancer Patients with Brain Metastasis

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR-IOR-17012098

**Population segments:** EGFR, Line of therapy N/A, Stage IV

**Phase:** II

**Therapies:** tyrosine kinase inhibitors, radiation therapy

**Location:** China

## EGFR A289T mutation (continued)

**NCT03706287**

Efficacy and Safety of Anlotinib Combined With Platinum Plus Pemetrexed in T790M Mutation Negative Metastatic Non-squamous Non-small-cell Lung Cancer After Progression on First-line EGFR TKI: a Phase II, Multi-center, Single Arm Study

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifier:** ALTER-L022

**Population segments:** Adenocarcinoma, EGFR, Large Cell, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** anlotinib hydrochloride, chemotherapy

**Location:** China

**NCT04993391**

A Dose-escalation, Dose-extension and Efficacy-extension, Phase I/II Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetic Profile and Preliminary Efficacy of AP-L1898 Capsule for the Treatment of the Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CTR20211347, JS111-001-I

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** AP-L1898

**Location:** China

**No NCT ID - see other identifier(s)**

A Multicenter, Single-Arm, Clinical Study of TQB2450 Plus Anlotinib in EGFR-Positive Non-Small Cell Lung Cancer Patients After Failure of EGFR TKI Therapy

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** ChiCTR1900026273

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** CBT-502, anlotinib hydrochloride

**Location:** China

**NCT03974022**

A Phase I/II, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Anti-tumor Efficacy of DZD9008 in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) With EGFR or HER2 Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 19-2390, 19-280, DZ2019E0001, NCI-2019-08532, UCI-19-65, WU-KONG1

**Population segments:** EGFR, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** I/II

**Therapy:** DZD-9008

**Locations:** Australia, Taiwan, United States

**US States:** CA, CO, MA

**Contact:** Dr. Li Zheng [li.zheng@dizalpharma.com]

## EGFR A289T mutation (continued)

**NCT03797391**

First-in-human, Phase I/II, Multicenter, Open-Label Study of EMB-01 in Patients With Advanced/Metastatic Solid Tumors

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CTR20190241, EMB01X101, NCI-2019-01391

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** EMB01

**Locations:** China, United States

**US States:** MA, MI, OH

**Contact:** Dr. YINGXI ZHANG [CT.info@epimab.com]

**No NCT ID - see other identifier(s)**

A phase I/II study of erlotinib/carboplatin/pemetrexed/bevacizumab in chemotherapy-naïve patients with EGFR mutation positive advanced non-squamous non-small-cell lung cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** UMIN000013202

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage III, Stage IV

**Exclusion criteria variant class:** EGFR T790M mutation (Non-Small Cell Lung Cancer)

**Phase:** I/II

**Therapies:** erlotinib, chemotherapy, bevacizumab

**Location:** Japan

**NCT03758287**

A Phase Ib, Multi-center, Open Label Study of Ningetinib (CT053PTSA) in Combination With Gefitinib in Stage IIIB or IV NSCLC Patients With EGFR Mutation and T790M Negative Who Have Progressed After EGFR TKI Therapy

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** EGFR T790M negative

**Other identifiers:** CTR20160875, PCD-DCT053-16-001

**Population segments:** EGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** ningetinib, gefitinib

**Location:** China

**No NCT ID - see other identifier(s)**

A Phase Ib/II Umbrella Study to Evaluate the Safety and Efficacy of Varlitinib in Combination with Weekly Paclitaxel in HER1/HER2 Co-Expressing Advanced or Metastatic Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** EGFR mutation

**Other inclusion criteria:** ERBB2 expression

**Other identifiers:** 4-2018-1011, KCT0003583, KM-13

**Population segments:** EGFR, HER2 negative, HER2 positive, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** varlitinib + chemotherapy

**Location:** Republic of Korea



## EGFR A289T mutation (continued)

**NCT03711422**

A Dose Finding Study of Continuous and Intermittent High-dose (HDI) Afatinib (EGFR TKI) on CNS Metastases and Leptomeningeal Disease (LMD) in Patients With Advanced Refractory EGFR Mutation Positive Non-small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** 1200.275

**Population segments:** CNS mets, EGFR, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** afatinib

**Location:** Singapore

**NCT02609776**

A Phase I, First-in-Human, Open-Label, Dose Escalation Study of JNJ-61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects With Advanced Non-Small Cell Lung Cancer.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 18137, 18-456, 19389, 61186372EDI1001, CHRYSALIS, CR108064, CTR20190589, EudraCT Number: 2018-003908-38, JapicCTI-184169, NCI-2018-00140, RWF\_61186372EDI1001, S17-01799

**Population segments:** EGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** amivantamab, chemotherapy

**Locations:** Australia, Canada, China, France, Japan, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** CA, FL, IL, MA, MD, MI, MN, MO, NY, OR, PA, VA

**NCT04528836**

A Phase I/IB First-in-Human Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Patients With Advanced Solid Tumors

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** NAV-1001

**Population segments:** Second line, Stage II, Stage III

**Exclusion criteria variant classes:** BRAF V600 mutation (Non-Small Cell Lung Cancer, Unspecified Solid Tumor), HRAS Q61 mutation (Non-Small Cell Lung Cancer, Unspecified Solid Tumor), KRAS Q61 mutation (Non-Small Cell Lung Cancer, Unspecified Solid Tumor), NRAS Q61 mutation (Non-Small Cell Lung Cancer, Unspecified Solid Tumor), PTPN11 activating mutation (Non-Small Cell Lung Cancer, Unspecified Solid Tumor)

**Phase:** I

**Therapy:** BBP-398

**Location:** United States

**US States:** CO, TX, UT

**Contact:** Vaeling Clinical Operations Lead [408-203-1726; vaeling.miller@bridgebio.com]

## EGFR A289T mutation (continued)

**No NCT ID - see other identifier(s)**

Feasibility Study of Pemetrexed / Bevacizumab / Erlotinib in Chemotherapy Naive Patients With Non- Small Cell Lung Cancer Harboring EGFR Mutation

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** UMIN000014477

**Population segments:** Adenocarcinoma, EGFR, First line, Large Cell, Stage III, Stage IV

**Exclusion criteria variant class:** EGFR T790M mutation (Non-Small Cell Lung Cancer)

**Phase:** I

**Therapy:** bevacizumab + erlotinib + chemotherapy

**Location:** Japan

**No NCT ID - see other identifier(s)**

Phase I Study of DZD9008 in EGFR or HER2 Mutant NSCLC Chinese Patients

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** CTR20192097, DZ2019E0002

**Population segments:** CNS mets, EGFR, HER2 positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** DZD-9008

**Location:** China

**NCT04077463**

An Open-label Phase I/Ib Study to Evaluate the Safety and Pharmacokinetics of JNJ-73841937 (Lazertinib), a Third Generation EGFR-TKI, as Monotherapy or in Combinations With JNJ-61186372, a Human Bispecific EGFR and cMet Antibody in Participants With Advanced Non-Small Cell Lung Cancer

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 20-492, 73841937NSC1001, AAAT1655, CHRYSALIS-2, CR108656, CTR20202097, EudraCT Number: 2020-000747-31, Janssen ChrysalisNSC 1001, JapicCTI-194934, NSC 1001, S20-00901

**Population segments:** EGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** lazertinib, amivantamab, chemotherapy

**Locations:** China, France, Germany, Italy, Japan, Puerto Rico, Republic of Korea, Spain, Taiwan, United States

**US States:** CA, FL, MA, MI, MO, NY, OR, PA, UT, VA, WA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

**NCT04013542**

A Pilot Trial of Ipilimumab-Nivolumab in Local-Regionally Advanced Non Small Cell Lung Cancer (NSCLC)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 2018-0836, NCI-2019-03205

**Population segments:** ALK, EGFR, First line, Maintenance/Consolidation, Stage II, Stage III

**Phase:** I

**Therapies:** nivolumab, ipilimumab, radiation therapy

**Location:** United States

**US State:** TX

**Contact:** Anne S. Tsao [713-792-6363; astsao@mdanderson.org]

## EGFR A289T mutation (continued)

**NCT04140526**

Safety, Pharmacokinetics (PK), and Efficacy of ONC-392 as a Single Agent and in Combination With Pembrolizumab in Advanced Solid Tumors and NSCLC: An Open Label Phase IA/IB Study. Preserve CTLA4 Checkpoint Function (PRESERVE-001)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** 20193108, NCI-2020-06149, ONC-392-001, PRESERVE-001

**Population segments:** ALK, EGFR, First line, Merkel, Pulmonary, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** ONC-392, osimertinib

**Location:** United States

**US States:** CA, MD, OH, UT

**Contact:** Dr. Pan Zheng [202-751-6823; pzheng@oncoc4.com]

**No NCT ID - see other identifier(s)**

Study Of Immunologic Factor In Re-Biopsy Specimen, Peritumoral BALF, And The Peripheral Blood For Predicting Response To Osimertinib In NSCLC Patients

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifier:** UMIN000023853

**Population segments:** EGFR, N/A, Second line or greater/Refractory/Relapsed

**Phase:** I

**Therapy:** osimertinib

**Location:** Japan

**No NCT ID - see other identifier(s)**

Pharmacokinetic and dose finding study of osimertinib in patients with impaired renal function and low body weight

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation

**Other identifiers:** jRCTs031180232, UMIN000033301

**Population segments:** EGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapy:** osimertinib

**Location:** Japan

**NCT03800134**

A Phase III, Double-blind, Placebo-controlled, Multi-center International Study of Neoadjuvant/Adjuvant Durvalumab for the Treatment of Patients With Resectable Stages II and III Non-small Cell Lung Cancer (AEGEAN)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR mutation status

**Other inclusion criteria:** CD274 expression status

**Other identifiers:** AEGEAN, CTR20200932, CTRI/2019/06/019634, D9106C00001, EudraCT Number: 2018-002997-29, JapicCTI-194656, NCI-2019-01822, NL72968.056.20, PHRR190321-002089, Pro00090077

**Population segments:** ALK, Adenocarcinoma, Adjuvant, EGFR, Large Cell, Neoadjuvant, Squamous Cell, Stage II, Stage III

**Phase:** III

**Therapies:** durvalumab, chemotherapy

**Locations:** Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Costa Rica, France, Germany, Hungary, India, Italy, Japan, Mexico, Netherlands, Peru, Philippines, Poland, Puerto Rico, Republic of Korea, Russian Federation, Spain, Taiwan, Thailand, United States, Viet Nam

**US States:** AZ, CA, FL, IL, KS, KY, MD, MN, NC, NJ, NY, OR, PA, SC, TX, VA, WA

**Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

## EGFR A289T mutation (continued)

**No NCT ID - see other identifier(s)**

A Pilot Study for Apatinib Mesylate Combined with Gefitinib in First-line Treatment of Lung Adenocarcinoma with Malignant Pleural Effusion or Pericardial Effusion

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR positive

**Other identifier:** ChiCTR1800017332

**Population segments:** Adenocarcinoma, EGFR, First line, N/A

**Phase:** IV

**Therapies:** apatinib, gefitinib

**Location:** China

**NCT04824079**

Study of Kenaitinib in Patients With Advanced Non-small Cell Lung Cancer With Brain Metastasis or Progression of Brain Metastasis After Treatment With EGFR Inhibitor(s)

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** EGFR positive

**Other identifiers:** CTR20200640, MEDO-007-20002

**Population segments:** CNS mets, EGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** keynatinib

**Location:** China

**NCT03542799**

Phase I/II Study of EGFR-IL12-CART Cells for Patients With Metastatic Colorectal Cancer

**Cancer type:** Colorectal Cancer

**Variant class:** EGFR positive

**Other identifiers:** CN-0093, EGFR CART, Protocol. PGCAR/EGFR012

**Population segments:** Line of therapy N/A, Stage IV

**Phase:** I/II

**Therapy:** CART-EGFR/IL12 (Pregene)

**Location:** China

**No NCT ID - see other identifier(s)**

A Phase Ib Study to Evaluate the Safety and Efficacy of Combination Therapy With Nivolumab and Photoimmunotherapy (PIT) Using ASP-1929 for the Patients With Unresectable Advanced / Recurrent Gastric Cancer or Esophageal Cancer

**Cancer type:** Esophageal Cancer, Gastric Cancer

**Variant class:** EGFR positive

**Other identifiers:** EPOC1901, GE-PIT, JapicCTI-194969

**Population segments:** EGFR, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** nivolumab, cetuximab sarotalocan

**Location:** Japan

## EGFR A289T mutation (continued)

**NCT03919292**

Phase 1/2 Study of Neratinib and Divalproex Sodium (Valproate) in Advanced Solid Tumors, With an Expansion Cohort in Ras-Mutated Cancers

**Cancer type:** Glioblastoma

**Variant class:** EGFR aberration

**Other identifiers:** MCC-17-13821, NCI-2019-02675

**Population segments:** KRAS, NRAS, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** neratinib, valproic acid

**Location:** United States

**US State:** VA

**Contact:** Caryn Weir [804-628-2310; cweir@vcu.edu]

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
EGFR A289T mutation	None	afatinib bevacizumab + erlotinib bevacizumab + gefitinib dacomitinib erlotinib erlotinib + ramucirumab gefitinib gefitinib + chemotherapy	90
<b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None			

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types
 ☒ No evidence

## EGFR A289T mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
afatinib	×	×	×	○	● (II)
erlotinib	×	×	×	○	● (II)
dacomitinib	×	×	×	○	○ (IV)
gefitinib	×	×	×	○	○ (II)
bevacizumab + erlotinib	×	×	×	○	×
bevacizumab + gefitinib	×	×	×	○	×
erlotinib + ramucirumab	×	×	×	○	×
gefitinib + carboplatin + pemetrexed	×	×	×	○	×

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### EGFR A289T mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
pirotinib	✕	✕	✕	✕	ⓘ (II)
poziotinib	✕	✕	✕	✕	ⓘ (II)
gefitinib, erlotinib, afatinib	✕	✕	✕	✕	● (II)
BCA101	✕	✕	✕	✕	● (I)
FT500, nivolumab, pembrolizumab, atezolizumab	✕	✕	✕	✕	● (I)
neratinib, palbociclib, everolimus, trametinib	✕	✕	✕	✕	● (I)
TQB 3804	✕	✕	✕	✕	● (I)
ZZ06	✕	✕	✕	✕	● (I)
afatinib, osimertinib	✕	✕	✕	✕	○ (IV)
apatinib + EGFR tyrosine kinase inhibitor	✕	✕	✕	✕	○ (IV)
apatinib, gefitinib	✕	✕	✕	✕	○ (IV)
EGFR tyrosine kinase inhibitor	✕	✕	✕	✕	○ (IV)
gefitinib, radiation therapy	✕	✕	✕	✕	○ (IV)
osimertinib	✕	✕	✕	✕	○ (IV)
atezolizumab, bevacizumab, chemotherapy	✕	✕	✕	✕	○ (III)
durvalumab, chemotherapy	✕	✕	✕	✕	○ (III)
icotinib hydrochloride, chemotherapy	✕	✕	✕	✕	○ (III)
almonertinib	✕	✕	✕	✕	○ (II)
almonertinib, chemotherapy	✕	✕	✕	✕	○ (II)
anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
anlotinib hydrochloride, chemotherapy	✕	✕	✕	✕	○ (II)
anlotinib hydrochloride, gefitinib	✕	✕	✕	✕	○ (II)
bevacizumab, osimertinib	✕	✕	✕	✕	○ (II)
dacomitinib, osimertinib	✕	✕	✕	✕	○ (II)
datopotamab deruxtecan	✕	✕	✕	✕	○ (II)
EGFR tyrosine kinase inhibitor + chemotherapy, EGFR tyrosine kinase inhibitor	✕	✕	✕	✕	○ (II)
EGFR tyrosine kinase inhibitor, radiation therapy	✕	✕	✕	✕	○ (II)
erlotinib, chemotherapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### EGFR A289T mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
famitinib, almonertinib	✕	✕	✕	✕	○ (II)
gefitinib, bevacizumab, chemotherapy	✕	✕	✕	✕	○ (II)
keynatinib	✕	✕	✕	✕	○ (II)
nazartinib, gefitinib	✕	✕	✕	✕	○ (II)
nivolumab	✕	✕	✕	✕	○ (II)
olaparib, durvalumab	✕	✕	✕	✕	○ (II)
osimertinib, chemotherapy	✕	✕	✕	✕	○ (II)
panitumumab	✕	✕	✕	✕	○ (II)
PD-1 Inhibitor, chemotherapy	✕	✕	✕	✕	○ (II)
sutetinib	✕	✕	✕	✕	○ (II)
targeted therapy, chemotherapy	✕	✕	✕	✕	○ (II)
tyrosine kinase inhibitors, radiation therapy	✕	✕	✕	✕	○ (II)
AP-L1898	✕	✕	✕	✕	○ (I/II)
BLU-945	✕	✕	✕	✕	○ (I/II)
brigatinib, panitumumab	✕	✕	✕	✕	○ (I/II)
CART-EGFR/IL12 (Pregene)	✕	✕	✕	✕	○ (I/II)
CBT-502, anlotinib hydrochloride	✕	✕	✕	✕	○ (I/II)
DZD-9008	✕	✕	✕	✕	○ (I/II)
EMB01	✕	✕	✕	✕	○ (I/II)
erlotinib, chemotherapy, bevacizumab	✕	✕	✕	✕	○ (I/II)
mobocertinib, chemotherapy	✕	✕	✕	✕	○ (I/II)
neratinib, valproic acid	✕	✕	✕	✕	○ (I/II)
ningetinib, gefitinib	✕	✕	✕	✕	○ (I/II)
quaratusugene ozeplasmid, osimertinib	✕	✕	✕	✕	○ (I/II)
varlitinib + chemotherapy	✕	✕	✕	✕	○ (I/II)
amivantamab, chemotherapy	✕	✕	✕	✕	○ (I)
BBP-398	✕	✕	✕	✕	○ (I)
bevacizumab + erlotinib + chemotherapy	✕	✕	✕	✕	○ (I)
lazertinib, amivantamab, chemotherapy	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types
 ☒ No evidence

### EGFR A289T mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
MRX-2843, osimertinib	×	×	×	×	○ (I)
niraparib, osimertinib	×	×	×	×	○ (I)
nivolumab, cetuximab sarotalocan	×	×	×	×	○ (I)
nivolumab, ipilimumab, radiation therapy	×	×	×	×	○ (I)
ONC-392, osimertinib	×	×	×	×	○ (I)
telaglenastat, sapanisertib	×	×	×	×	○ (I)
TNO-155, nazartinib	×	×	×	×	○ (I)
WSD-0922	×	×	×	×	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>EGFR A289T mutation</i>	None	afatinib bevacizumab + erlotinib bevacizumab + gefitinib dacomitinib erlotinib erlotinib + ramucirumab gefitinib gefitinib + chemotherapy	90
<b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None			

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### EGFR A289T mutation

NCT ID	Title	Phase
NCT04172597	A Phase II Study of Pozitotinib in Patients With EGFR or HER2 Activating Mutations in Advanced Malignancies	II
NCT02465060	Molecular Analysis for Therapy Choice (MATCH).	II
NCT03810872	An Open Explorative Phase II, Open Label Study of Afatinib in the Treatment of Advanced Cancer Carrying an EGFR, a HER2 or a HER3 Mutation	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II

**Disclaimer:** The data presented here is from a curated knowledgebase of publicly available information, but may not be exhaustive. The data version is 2021.11(003).



## Clinical Trials Summary (continued)

### EGFR A289T mutation (continued)

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT03065387	Phase I Study of the Pan-ERBB Inhibitor Neratinib Given in Combination With Everolimus, Palbociclib, or Trametinib in Advanced Cancer Subjects With EGFR Mutation/Amplification, HER2 Mutation/Amplification, or HER3/4 Mutation or KRAS Mutation	I
No NCT ID	Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment	I
NCT04128085	A Phase I, Open-label, Multicenter, Dose Escalation and Expansion Study to Evaluate the Tolerance and Pharmacokinetics of TQB3804 in Subjects With Advanced Malignant Tumors	I
NCT03841110	FT500 as Monotherapy and in Combination With Immune Checkpoint Inhibitors in Subjects With Advanced Solid Tumors (Phase I)	I
NCT04412616	A Phase I, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Preliminary Evidence of Antitumor Activity of ZZ06 in Adult Patients With Advanced EGFR Positive Solid Tumor Malignancies	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04429542	First-in-Human, Phase I/Ib, Open-label, Multicenter Study of Bifunctional EGFR/TGFβ Fusion Protein BCA101 Alone and in Combination With Pembrolizumab in Patients With EGFR-Driven Advanced Solid Tumors	I
NCT04511533	Single Arm Study to Evaluate the Safety of Dacomitinib for the First-Line Treatment of Participants in India With Metastatic Non-Small Cell Lung Cancer With Epidermal Growth Factor Receptor (EGFR)-Activating Mutations	IV
No NCT ID	The Continuous Evaluation of EGFR Mutation in EGFR-mutation Positive Lung Cancer Patients During EGFR TKI Treatment.	IV
NCT03991403	Study of Atezolizumab in Combination With Carboplatin + Paclitaxel + Bevacizumab vs With Pemetrexed + Cisplatin or Carboplatin With Stage IV Non-Squamous Non-Small Cell Lung Cancer with EGFR (+) or ALK (+)	III
NCT03088059	A Pilot Study of Personalized Biomarker-based Treatment Strategy or Immunotherapy in Patients With Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck	II
NCT04147351	A Phase II Study of Atezolizumab in Combination With Bevacizumab, Carboplatin or Cisplatin, and Pemetrexed for EGFR-mutant Metastatic Non-small Cell Lung Cancer Patients After Failure of EGFR Tyrosine Kinase Inhibitors.	II
NCT04811001	A Randomised Non-comparative, Phase II Study Investigating the Best Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR-TKI) Sequence in Advanced or Metastatic Non Small-Cell Lung Cancer (NSCLC) Harboring EGFR Mutations	II
NCT04484142	Phase II, Single-arm, Open-label Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations and Progressed On or After Applicable Targeted Therapy and Platinum Based Chemotherapy (TROPION-Lung05)	II
No NCT ID	ITAC 2 TRIAL: Intermittent TKI and Chemotherapy for Patients with Advanced Non-Small Cell Lung Cancer	II
NCT03151161	A Prospective, Multi-center, Open-labeled Phase II Randomized and Comparative Clinical Study of First Line Intermittent and Maintenance of Icotinib in Combination With Pemetrexed/Carboplatin Compared With Icotinib Single Drug in IIIB/IV Non Small Cell Lung Cancer With Epidermal Growth Factor Receptor (EGFR) Mutation	II
NCT03292133	A Phase II Study of EGF816 and Gefitinib in TKI-naive EGFR-mutant Non-Small Cell Lung Cancer	II

## Clinical Trials Summary (continued)

### EGFR A289T mutation (continued)

NCT ID	Title	Phase
NCT04335292	Osimertinib Then Chemotherapy in EGFR-mutated Lung Cancer With Osimertinib Third-line Rechallenge	II
NCT04410796	A Phase II Randomized Study of Osimertinib Versus Osimertinib Plus Chemotherapy for Patients With Metastatic EGFR-Mutant Lung Cancers That Have Detectable EGFR-Mutant cfDNA in Plasma After Initiation of Osimertinib	II
NCT03318939	A Phase II Study of Pozitotinib in Patients With Non-Small Cell Lung Cancer (NSCLC), Locally Advanced or Metastatic, With EGFR or HER2 Exon 20 Insertion Mutation (ZENITH20).	II
NCT04862780	A Phase I/II Study Targeting Acquired Resistance Mechanisms in Patients With EGFR Mutant Non-Small Cell Lung Cancer	I/II
No NCT ID	Phase I/II Study of Brigatinib plus Panitumumab in Patients with Advanced EGFR-mutated Non-small Cell Lung Cancer Harboring C797S Resistant Mutation to Osimertinib	I/II
NCT02716116	A Phase I/II Study of the Safety, Pharmacokinetics, and Anti-Tumor Activity of the Oral EGFR/HER2 Inhibitor TAK-788 (AP32788) in Non-Small Cell Lung Cancer.	I/II
NCT04486833	A Phase I/II Open-Label, Dose-escalation and Clinical Response Study of GPX-001 in Combination With Osimertinib in Patients With Advanced, Metastatic EGFR-mutant Non-small Cell Lung Cancer	I/II
No NCT ID	A Phase I Study Afatinib In Combination Of Osimertinib In Patients With Relapsed Non-Small Cell Lung Cancer After Failure of Prior Osimertinib	I
NCT03755102	A Pilot Study of Dacomitinib With or Without Osimertinib for Patients With Metastatic EGFR Mutant Lung Cancers With Disease Progression on Osimertinib	I
NCT04762199	A Phase Ib Safety and Pharmacodynamic Study of MER Tyrosine Kinase Inhibitor, MRX-2843, in Combination With Osimertinib in Advanced EGFR Mutant Non-Small Cell Lung Cancer	I
NCT03891615	Phase I Study of Niraparib in Combination With Osimertinib in EGFR-Mutated Advanced Lung Cancer	I
NCT04250545	A Phase I Trial of MLN0128 (Sapanisertib) and CB-839 HCl (Telaglenastat) in Advanced NSCLC Patients	I
NCT03114319	An Open-label, Multi-center, Phase I, Dose Finding Study of Oral TNO155 in Adult Patients With Advanced Solid Tumors.	I
NCT04197934	Phase I Study to Evaluate Safety, Tolerability, Pharmacokinetics and Anti-Tumor Activity of WSD0922-FUFU	I
NCT04413201	AFAMOSI: Prospective, Randomized, Multicenter Phase IV Study to Evaluate the Efficacy and Safety of Afatinib Followed by Osimertinib Compared to Osimertinib in Patients With EGFRmutated/T790M Mutation Negative Non-squamous NSCLC in the First-line Setting	IV
No NCT ID	Apatinib Combined With EGFR-TKI For Patients With EGFR Mutation Who Failed EGFR-TKI: A Prospective Study	IV
No NCT ID	A Real World Study Of Apatinib Combined With Gefitinib In The Treatment Of EGFRm+ Advanced Non-Squamous Non-Small Cell Lung Cancer	IV
No NCT ID	Clinical Study Of Combined Action Of Gefitinib And Brain Radiotherapy On EGFR-Mutated Non-Small-Cell Lung Cancer Patients With Brain Metastasis	IV
No NCT ID	A Multicenter, Open-Label, Single Arm Pilot Study: Osimertinib As Neoadjuvant Treatment For Resectable Stage II-IIIa EGFR Mutant Lung Adenocarcinoma.	IV
NCT03992885	Combination Therapy With Icotinib, Pemetrexed and Platinum in Patients With Metastatic Non-squamous Non-small Cell Lung Cancer With EGFR Mutations Who Did Not Progress After Pemetrexed in Combination With Platinum-based Chemotherapy: a Single-arm, Open, Multicenter Clinical Study.	III

## Clinical Trials Summary (continued)

### EGFR A289T mutation (continued)

NCT ID	Title	Phase
No NCT ID	A Phase II Study Of Afatinib For Advanced Non-Small Cell Lung Cancer With Uncommon Epidermal Growth Factor Receptor (EGFR) Mutation Including Compound Mutation Detected By Next Generation Sequencing	II
NCT04785742	An Open, Multicenter Phase II Clinical Study to Evaluate the Safety and Efficacy of Almonertinib in Patients With Advanced NSCLC With Rare Mutations in EGFR	II
No NCT ID	Safety and efficacy analysis of Ametinib combined with Pemetrexed intraoperatively for treatment of EGFR mutant lung cancer with meningeal metastases after first-line TKI failure	II
No NCT ID	A Single-center, Open Label, Phase II Study of Anlotinib as Second/Third-line Treatment for Advanced Non-small Cell Lung Cancer	II
NCT04619563	A Single-arm Exploratory Clinical Study of Anlotinib Hydrochloride Combined With Docetaxel in EGFR Mutations Advanced Non Small Cell Lung Cancer Patients Who Have Progressed After Targeted Therapy and Chemotherapy	II
No NCT ID	Clinical Study And Safety Analysis On The Treatment Of Advanced Non-Small Cell Lung Cancer With Anlotinib And Gefitinib	II
NCT04245085	A Randomised Non-comparative Open Label Phase II Trial of Atezolizumab Plus Bevacizumab, With Carboplatin-paclitaxel or Pemetrexed, in EGFR-mutant Non-small Cell Lung Carcinoma With Acquired Resistance	II
No NCT ID	Osimertinib Combined Bevacizumab in Untreated Epidermal Growth Factor Receptor Mutated Non-small-cell Lung Cancer Patients with Malignant Pleural And/Or Pericardial Effusion -phase II Trial	II
No NCT ID	Randomized Controlled Trial for EGFR-TKIs Plus S-1 or EGFR-TKIs as the First-Line Therapy for Patients with Advanced Non-small Cell Lung Cancer Harboring EGFR Mutations	II
No NCT ID	EGFR-TKI Combined With Stereotactic Body Radiation Therapy Versus TKI alone for Stage IV Oncogene-Driven Non-Small Cell Lung Cancer.	II
NCT03904823	An Open, Single-arm, Multi-center, Phase II Clinical Trial of Famitinib Combined With Epidermal Growth Factor Receptor (EGFR) Inhibitor HS-10296 in Patients With Advanced EGFR-mutant Non-Small Cell Lung Cancer (NSCLC)	II
NCT01784549	A Multi-center Phase II Randomized Study of Customized Neoadjuvant Therapy Versus Standard Chemotherapy in Non-small Cell Lung Cancer (NSLC) Patients With Resectable Stage IIIA (N2) Disease	II
No NCT ID	Gefitinib Plus Pemetrexed Combined With Bevacizumab Or Carboplatin In First-Line Treatment Of Stage IV EGFR Mutant Non-Squamous Non-Small Cell Lung Cancer	II
No NCT ID	Open-Label, Single arm, Phase II trial to Evaluate Efficacy and Safety of Nivolumab as Maintenance Therapy Following Platinum-based Chemotherapy in Non-Small Cell Lung Cancer Patients after Tyrosine Kinase Inhibitor Therapy	II
NCT04538378	Phase II Trial of Olaparib (LYNPARZA) Plus Durvalumab (IMFINZI) in EGFR-Mutated Adenocarcinomas That Transform to Small Cell Lung Cancer (SCLC) and Other Neuroendocrine Tumors.	II
No NCT ID	Phase II trial of osimertinib for rare EGFR mutation-positive non-small cell lung cancer	II
NCT03460275	Osimertinib as First-line Therapy for Patients With EGFR Mutation-positive Locally Advanced or Metastatic Non-squamous Non-Small Cell Lung Cancer(NSCLC), a Single-Arm, Open-Label, Prospective, Multicenter, Phase II Clinical Trial	II
No NCT ID	Efficacy Of Osimertinib With Platinum And Pemetrexed In EGFR Mutant Non-Small Cell Lung Cancer Patients Bearing CNS Metastasis, And Have Systemic Progression But Stable Intracranial Disease On Osimertinib Resistance. (EPONA)	II

## Clinical Trials Summary (continued)

### EGFR A289T mutation (continued)

NCT ID	Title	Phase
NCT03087071	A Phase II Enrichment Study of Panitumumab as a Single Agent or in Combination With Trametinib in Anti-EGFR-Refractory Stage IV Colorectal Cancer Patients	II
No NCT ID	An Exploratory Clinical Study Of PD-1 Inhibitor Combined With Chemotherapy In The Treatment Of Advanced Non-small Cell Lung Cancer With EGFR Mutation Positive And T790M Negative After Failure Of TKI Combined With Antiangiogenic Drugs	II
NCT03574402	An Open-label, Multi-center, Phase II Umbrella Study to Assess Efficacy of Targeted Therapy or Immunotherapy Directed by Next Generation Sequencing (NGS) in Chinese Patients With Advanced NSCLC (TRUMP)	II
No NCT ID	A Multicenter, Open-label Phase IIb Clinical Study to Evaluate the Efficacy and Safety of SZMD in Patients with Locally Advanced or Metastatic Lung Cancer (Non-resistant Rare EGFR Mutations Only, Including L861Q, G719X and/or S768I)	II
No NCT ID	A Single-Center, Open-Label , Non-Randomized Control Clinical Trial On Clinical Features And Medical Treatment Of Advanced NSCLC With Rare Gene Mutations	II
No NCT ID	Clinical Study of Combined Action of the First Generation of TKIs and Brain Radiotherapy on EGFR-Mutated Non-Small-Cell Lung Cancer Patients with Brain Metastasis	II
NCT03706287	Efficacy and Safety of Anlotinib Combined With Platinum Plus Pemetrexed in T790M Mutation Negative Metastatic Non-squamous Non-small-cell Lung Cancer After Progression on First-line EGFR TKI: a Phase II, Multi-center, Single Arm Study	I/II
NCT04993391	A Dose-escalation, Dose-extension and Efficacy-extension, Phase I/II Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetic Profile and Preliminary Efficacy of AP-L1898 Capsule for the Treatment of the Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer	I/II
No NCT ID	A Multicenter, Single-Arm, Clinical Study of TQB2450 Plus Anlotinib in EGFR-Positive Non-Small Cell Lung Cancer Patients After Failure of EGFR TKI Therapy	I/II
NCT03974022	A Phase I/II, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Anti-tumor Efficacy of DZD9008 in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) With EGFR or HER2 Mutation	I/II
NCT03797391	First-in-human, Phase I/II, Multicenter, Open-Label Study of EMB-01 in Patients With Advanced/ Metastatic Solid Tumors	I/II
No NCT ID	A phase I/II study of erlotinib/carboplatin/pemetrexed/bevacizumab in chemotherapy-naive patients with EGFR mutation positive advanced non-squamous non-small-cell lung cancer	I/II
NCT03758287	A Phase Ib, Multi-center, Open Label Study of Nintedanib (CT053PTSA) in Combination With Gefitinib in Stage IIIB or IV NSCLC Patients With EGFR Mutation and T790M Negative Who Have Progressed After EGFR TKI Therapy	I/II
No NCT ID	A Phase Ib/II Umbrella Study to Evaluate the Safety and Efficacy of Varlitinib in Combination with Weekly Paclitaxel in HER1/HER2 Co-Expressing Advanced or Metastatic Gastric Cancer	I/II
NCT03711422	A Dose Finding Study of Continuous and Intermittent High-dose (HDI) Afatinib (EGFR TKI) on CNS Metastases and Leptomeningeal Disease (LMD) in Patients With Advanced Refractory EGFR Mutation Positive Non-small Cell Lung Cancer	I
NCT02609776	A Phase I, First-in-Human, Open-Label, Dose Escalation Study of JNJ-61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects With Advanced Non-Small Cell Lung Cancer.	I
NCT04528836	A Phase I/IB First-in-Human Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Patients With Advanced Solid Tumors	I

## Clinical Trials Summary (continued)

### EGFR A289T mutation (continued)

NCT ID	Title	Phase
No NCT ID	Feasibility Study of Pemetrexed / Bevacizumab / Erlotinib in Chemotherapy Naive Patients With Non-Small Cell Lung Cancer Harboring EGFR Mutation	I
No NCT ID	Phase I Study of DZD9008 in EGFR or HER2 Mutant NSCLC Chinese Patients	I
NCT04077463	An Open-label Phase I/Ib Study to Evaluate the Safety and Pharmacokinetics of JNJ-73841937 (Lazertinib), a Third Generation EGFR-TKI, as Monotherapy or in Combinations With JNJ-61186372, a Human Bispecific EGFR and cMet Antibody in Participants With Advanced Non-Small Cell Lung Cancer	I
NCT04013542	A Pilot Trial of Ipilimumab-Nivolumab in Local-Regionally Advanced Non Small Cell Lung Cancer (NSCLC)	I
NCT04140526	Safety, Pharmacokinetics (PK), and Efficacy of ONC-392 as a Single Agent and in Combination With Pembrolizumab in Advanced Solid Tumors and NSCLC: An Open Label Phase IA/IB Study. Preserve CTLA4 Checkpoint Function (PRESERVE-001)	I
No NCT ID	Study Of Immunologic Factor In Re-Biopsy Specimen, Peritumoral BALF, And The Peripheral Blood For Predicting Response To Osimertinib In NSCLC Patients	I
No NCT ID	Pharmacokinetic and dose finding study of osimertinib in patients with impaired renal function and low body weight	I
NCT03800134	A Phase III, Double-blind, Placebo-controlled, Multi-center International Study of Neoadjuvant/Adjuvant Durvalumab for the Treatment of Patients With Resectable Stages II and III Non-small Cell Lung Cancer (AEGEAN)	III
No NCT ID	A Pilot Study for Apatinib Mesylate Combined with Gefitinib in First-line Treatment of Lung Adenocarcinoma with Malignant Pleural Effusion or Pericardial Effusion	IV
NCT04824079	Study of Kenaitinib in Patients With Advanced Non-small Cell Lung Cancer With Brain Metastasis or Progression of Brain Metastasis After Treatment With EGFR Inhibitor(s)	II
NCT03542799	Phase I/II Study of EGFR-IL12-CART Cells for Patients With Metastatic Colorectal Cancer	I/II
No NCT ID	A Phase Ib Study to Evaluate the Safety and Efficacy of Combination Therapy With Nivolumab and Photoimmunotherapy (PIT) Using ASP-1929 for the Patients With Unresectable Advanced / Recurrent Gastric Cancer or Esophageal Cancer	I
NCT03919292	Phase 1/2 Study of Neratinib and Divalproex Sodium (Valproate) in Advanced Solid Tumors, With an Expansion Cohort in Ras-Mutated Cancers	I/II

## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 G370C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3 R248C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3 S249C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3-TACC3 fusion</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	31
<i>FGFR3-BAIAP2L1 fusion</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	30
<i>FGFR3 Y373C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	29
<i>FGFR3 K650E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	33
<i>FGFR3 K650M mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650Q mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650T mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 activating mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 K652E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 fusion</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	27
<i>FGFR3 A391E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	26
<i>FGFR3 KD mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V555 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V557 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 amplification</i> Prognostic significance: None Diagnostic significance: None	None	None	21
<i>FGFR3 aberration</i> Prognostic significance: None Diagnostic significance: None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO



## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

#### FGFR3 G370C mutation

##### ☐ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3 G370C mutation

##### Indications and usage:

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

##### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)

#### FGFR3 R248C mutation

##### ☐ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3 R248C mutation

##### Indications and usage:

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

##### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)



## FGFR3 S249C mutation

### ○ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3 S249C mutation

**Indications and usage:**

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)

## FGFR3-TACC3 fusion

### ○ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3-TACC3 fusion

**Indications and usage:**

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)

## FGFR3-BAIAP2L1 fusion

### ○ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3-BAIAP2L1 fusion

**Indications and usage:**

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)

## FGFR3 Y373C mutation

### ○ erdafitinib

**Cancer type:** Bladder Urothelial Carcinoma

**Label as of:** 2020-04-02

**Variant class:** FGFR3 Y373C mutation

**Indications and usage:**

BALVERSA® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212018s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212018s001lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### FGFR3 G370C mutation

#### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3 G370C mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

### FGFR3 R248C mutation

#### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3 R248C mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

### FGFR3 S249C mutation

#### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3 S249C mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

## FGFR3-TACC3 fusion

### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3-TACC3 fusion

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

## FGFR3-BAIAP2L1 fusion

### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3-BAIAP2L1 fusion

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

## FGFR3 Y373C mutation

### ☐ erdafitinib

Cancer type: Bladder Cancer

Variant class: FGFR3 Y373C mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Stage IV; Locally Advanced, Metastatic (Second-line therapy); Preferred intervention, Other recommended intervention
- Stage IV; Locally Advanced, Metastatic (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Bladder Cancer [Version 4.2021]

## Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2021-10-01. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### FGFR3 G370C mutation

#### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

### FGFR3 R248C mutation

#### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

### FGFR3 S249C mutation

#### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3-TACC3 fusion

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 fusion

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3-BAIAP2L1 fusion

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 fusion

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 Y373C mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 K650E mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 K650M mutation

### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 K650Q mutation

### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 K650T mutation

### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 activating mutation

### ☐ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 K652E mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 fusion

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma Variant class: FGFR3 fusion

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 A391E mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 KD mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]



## FGFR3 mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 V555 mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]

## FGFR3 V557 mutation

### ○ erdafitinib

Cancer type: Bladder Urothelial Carcinoma

Variant class: FGFR3 mutation

ESMO Level of Evidence/Grade of Recommendation: III / B


Population segment (Line of therapy):

- Advanced, Metastatic, Refractory (Subsequent therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Bladder Cancer [Ann Oncol (2014) 25 (suppl 3): iii40-iii48. (eUpdate: 16 July 2020, 16 December 2019, 16 December 2019)]


## Alerts Informed By Public Data Sources

### Current FDA Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

### FGFR3 G370C mutation

#### vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

#### Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

### FGFR3 R248C mutation

#### vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 R248C mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 S249C mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3-TACC3 fusion

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3-TACC3 fusion (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3-BAIAP2L1 fusion

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 Y373C mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 Y373C mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 K650E mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 K650M mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 K650M mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 K650Q mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 K650T mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 K650T mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 activating mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 K652E mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 K652E mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 fusion

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 A391E mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>



## FGFR3 A391E mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 KD mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 mutation (continued)

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 V555 mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

### **A** Debio 1347

**Cancer type:** Solid Tumor

**Variant class:** FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 V557 mutation

### **A** vofatamab

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR3-targeted monoclonal antibody, vofatamab, for FGFR3 mutations or fusions in advanced or metastatic urothelial carcinoma.

**Reference:**

<https://www.healio.com/news/hematology-oncology/20190107/fda-grants-fast-track-designation-to-vofatamab-for-bladder-cancer-subset>

## FGFR3 V557 mutation (continued)

### **A** Debio 1347

Cancer type: Solid Tumor

Variant class: FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 amplification

### **A** Debio 1347

Cancer type: Solid Tumor

Variant class: FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## FGFR3 aberration

### **A** Debio 1347

Cancer type: Solid Tumor

Variant class: FGFR3 aberration

**Supporting Statement:**

The FDA has granted Fast Track Designation to the FGFR 1-3 inhibitor, debio 1347, for FGFR1/2/3 alterations in unresectable or metastatic solid tumors.

**Reference:**

<https://www.debiopharm.com/drug-development/press-releases/fda-grants-fast-track-designation-to-debiopharm-internationals-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration/>

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### FGFR3 G370C mutation

#### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

#### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

#### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 G370C mutation (continued)

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## FGFR3 G370C mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

## FGFR3 G370C mutation (continued)

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 G370C mutation

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 G370C mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 G370C mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 G370C mutation

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 G370C mutation

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China



## FGFR3 G370C mutation (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [[manuel.haeckl@basilea.com](mailto:manuel.haeckl@basilea.com)]

## FGFR3 G370C mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3 G370C mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 G370C mutation (continued)

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; [clinicaltrials@QEDTx.com](mailto:clinicaltrials@QEDTx.com)]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

## FGFR3 G370C mutation (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

## FGFR3 G370C mutation (continued)

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 R248C mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 R248C mutation (continued)

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

## FGFR3 R248C mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea



## FGFR3 R248C mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 R248C mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 R248C mutation

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 R248C mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 R248C mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 R248C mutation

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 R248C mutation

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China

## FGFR3 R248C mutation (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [[manuel.haeckl@basilea.com](mailto:manuel.haeckl@basilea.com)]

**FGFR3 R248C mutation (continued)****NCT04053322**

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

**NCT03827850**

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

**NCT04601857**

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3 R248C mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 R248C mutation (continued)

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

## FGFR3 R248C mutation (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan



## FGFR3 R248C mutation (continued)

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 S249C mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 S249C mutation (continued)

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

## FGFR3 S249C mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

## FGFR3 S249C mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 S249C mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 S249C mutation

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 S249C mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 S249C mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 S249C mutation

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 S249C mutation

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China

## FGFR3 S249C mutation (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckel [[manuel.haeckel@basilea.com](mailto:manuel.haeckel@basilea.com)]

## FGFR3 S249C mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]



## FGFR3 S249C mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 S249C mutation (continued)

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

## FGFR3 S249C mutation (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

## FGFR3 S249C mutation (continued)

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3-TACC3 fusion

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TiFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04189445

A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-004084-49, JapicCTI-205312, NCI-2020-03407, NL73545.056.20, TAS-120-202, UW20046

**Population segments:** (N/A), Aggressive, Classical, FGFR, Indolent, Nodular lymphocyte-predominant, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** FGFR1 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR2 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR3 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR4 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma)

**Phase:** II

**Therapy:** futibatinib

**Locations:** Japan, Republic of Korea, United Kingdom, United States

**US States:** AZ, CA, TX, WI

**Contact:** Dr. Osamu Takahashi [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3-TACC3 fusion (continued)

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR fusion

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3-TACC3 fusion (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

## FGFR3-TACC3 fusion (continued)

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-TACC3 fusion

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-TACC3 fusion

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-TACC3 fusion

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China

## FGFR3-TACC3 fusion (continued)

### NCT04424966

A Phase 0 Study of Infigratinib in Recurrent High-Grade Glioma Participants Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration With PK Triggered Expansion Cohort

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** FGFR3-TACC3 fusion

**Other identifiers:** 2020-08, 20-500-092-34-38

**Population segments:** (N/A), Neoadjuvant

**Phase:** I

**Therapy:** infigratinib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]



## FGFR3-TACC3 fusion (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 fusion

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3-TACC3 fusion (continued)

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haeckl@basilea.com]

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR fusion

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3-TACC3 fusion (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR fusion

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3-TACC3 fusion (continued)

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3-TACC3 fusion (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3-BAIAP2L1 fusion

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04189445

A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-004084-49, JapicCTI-205312, NCI-2020-03407, NL73545.056.20, TAS-120-202, UW20046

**Population segments:** (N/A), Aggressive, Classical, FGFR, Indolent, Nodular lymphocyte-predominant, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** FGFR1 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR2 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR3 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR4 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma)

**Phase:** II

**Therapy:** futibatinib

**Locations:** Japan, Republic of Korea, United Kingdom, United States

**US States:** AZ, CA, TX, WI

**Contact:** Dr. Osamu Takahashi [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

## FGFR3-BAIAP2L1 fusion (continued)

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR fusion

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

## FGFR3-BAIAP2L1 fusion (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-BAIAP2L1 fusion

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-BAIAP2L1 fusion

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX



## FGFR3-BAIAP2L1 fusion (continued)

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3-BAIAP2L1 fusion

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 fusion

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haeckl@basilea.com]

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR fusion

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR fusion

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3-BAIAP2L1 fusion (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 Y373C mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 Y373C mutation (continued)

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [[pam.mangat@asco.org](mailto:pam.mangat@asco.org)]

## FGFR3 Y373C mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China



## FGFR3 Y373C mutation (continued)

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT03390504

A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 Y373C mutation

**Other identifiers:** 2018-0027, 42756493BLC3001, 42756493-BLC3001, CR108401, CTR20182097, CTRI/2018/07/014718, EudraCT Number: 2017-002932-18, INT2, IRAS ID 238051, JapicCTI-183949, JNJ-42756493, NCI-2018-01443, NL64531.091.18, THOR

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** III

**Therapies:** erdafitinib, pembrolizumab

**Locations:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Greece, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Poland, Portugal, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, Ukraine, United Kingdom, United States

**US States:** CA, DC, FL, IL, KY, MD, NC, NH, NV, NY, OH, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 Y373C mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 Y373C mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT02365597

A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 Y373C mutation

**Other identifiers:** 42756493BLC2001, BLC2001, CR105065, DRKS00009448, EudraCT Number: 2014-002408-26, IRAS ID 177346, NCI-2015-00818, REec-2015-1451

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** erdafitinib

**Locations:** France, Spain, United States

**US State:** TX

### NCT04492293

A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 Y373C mutation

**Other identifiers:** CTR20200688, ICP-CL-00302

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** ICP-192

**Location:** China

## FGFR3 Y373C mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3 Y373C mutation (continued)

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 Y373C mutation (continued)

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 Y373C mutation (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 K650E mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

## FGFR3 K650E mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 K650E mutation (continued)

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy



## FGFR3 K650E mutation (continued)

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

## FGFR3 K650E mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 K650E mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

## FGFR3 K650E mutation (continued)

### NCT04424966

A Phase 0 Study of Infigratinib in Recurrent High-Grade Glioma Participants Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration With PK Triggered Expansion Cohort

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** FGFR3 K650E mutation

**Other identifiers:** 2020-08, 20-500-092-34-38

**Population segments:** (N/A), Neoadjuvant

**Phase:** I

**Therapy:** infigratinib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K650E mutation (continued)

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haackl@basilea.com]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3 K650E mutation (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 K650E mutation (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K650E mutation (continued)

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 K650E mutation (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 K650M mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China



## FGFR3 K650M mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 K650M mutation (continued)

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3 K650M mutation (continued)

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

## FGFR3 K650M mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 K650M mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

## FGFR3 K650M mutation (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckel [[manuel.haeckel@basilea.com](mailto:manuel.haeckel@basilea.com)]

## FGFR3 K650M mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3 K650M mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 K650M mutation (continued)

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland



## FGFR3 K650M mutation (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

## FGFR3 K650M mutation (continued)

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 K650Q mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K650Q mutation (continued)

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

## FGFR3 K650Q mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

## FGFR3 K650Q mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 K650Q mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 K650Q mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

## FGFR3 K650Q mutation (continued)

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [[manuel.haeckl@basilea.com](mailto:manuel.haeckl@basilea.com)]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## FGFR3 K650Q mutation (continued)

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea



## FGFR3 K650Q mutation (continued)

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

## FGFR3 K650Q mutation (continued)

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; [JNJ.CT@sylogent.com](mailto:JNJ.CT@sylogent.com)]

## FGFR3 K650Q mutation (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 K650T mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K650T mutation (continued)

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

## FGFR3 K650T mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

## FGFR3 K650T mutation (continued)

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

## FGFR3 K650T mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 K650T mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## FGFR3 K650T mutation (continued)

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haackl@basilea.com]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3 K650T mutation (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 K650T mutation (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K650T mutation (continued)

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 K650T mutation (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 activating mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

## FGFR3 activating mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 activating mutation (continued)

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3 activating mutation (continued)

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]



## FGFR3 activating mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 activating mutation (continued)

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haackl@basilea.com]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3 activating mutation (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 activating mutation (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 activating mutation (continued)

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 activating mutation (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 K652E mutation

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 activating mutation

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China

## FGFR3 K652E mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 K652E mutation (continued)

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR activating mutation

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy



## FGFR3 K652E mutation (continued)

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

## FGFR3 K652E mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 activating mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K652E mutation (continued)

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 activating mutation

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haackl@basilea.com]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating mutation

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3 K652E mutation (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 K652E mutation (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 K652E mutation (continued)

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 K652E mutation (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 fusion

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 fusion (continued)

### NCT04189445

A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-004084-49, JapicCTI-205312, NCI-2020-03407, NL73545.056.20, TAS-120-202, UW20046

**Population segments:** (N/A), Aggressive, Classical, FGFR, Indolent, Nodular lymphocyte-predominant, Second line, Stage III, Stage IV, Third line

**Exclusion criteria variant classes:** FGFR1 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR2 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR3 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma), FGFR4 fusion (Central Nervous System Neoplasm, Intrahepatic Cholangiocarcinoma)

**Phase:** II

**Therapy:** futibatinib

**Locations:** Japan, Republic of Korea, United Kingdom, United States

**US States:** AZ, CA, TX, WI

**Contact:** Dr. Osamu Takahashi [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT05019794

A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** CTR20210275, LB1001-201

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Location:** China



## FGFR3 fusion (continued)

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR fusion

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

## FGFR3 fusion (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

## FGFR3 fusion (continued)

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 fusion

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3 fusion (continued)

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 fusion

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### NCT04045613

An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 fusion

**Other inclusion criteria:** CD274 expression

**Other identifiers:** CSET 3012, DZB-CS-201, EudraCT Number: 2019-000359-15, FIDES-02, NCI-2019-08162, RECF4112, SNCTP000004480

**Population segments:** FGFR, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** derazantinib, atezolizumab

**Locations:** Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Hungary, Italy, Poland, Republic of Korea, Spain, Switzerland, United Kingdom, United States

**US States:** GA, IL, KS, KY, NY, SC, TX, VA, WA

**Contact:** Dr. Manuel Häckl [manuel.haeckl@basilea.com]

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 fusion

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR fusion

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

## FGFR3 fusion (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR fusion

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 fusion (continued)

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

## FGFR3 fusion (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 A391E mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 A391E mutation (continued)

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [[pam.mangat@asco.org](mailto:pam.mangat@asco.org)]



## FGFR3 A391E mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

**FGFR3 A391E mutation (continued)****NCT04565275**

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

**No NCT ID - see other identifier(s)**

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

**No NCT ID - see other identifier(s)**

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

## FGFR3 A391E mutation (continued)

### NCT04197986

Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 A391E mutation

**Other identifiers:** EudraCT Number: 2019-003248-63, NCI-2020-00610, PROOF 302, QBGJ398-302

**Population segments:** Adjuvant, FGFR, Stage II, Stage III

**Exclusion criteria variant classes:** FGFR3 A391E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 G370C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650E mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650M mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650Q mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 K650T mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 R248C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 S249C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 Y373C mutation (Bladder Small Cell Neuroendocrine Carcinoma), FGFR3 fusion (Bladder Small Cell Neuroendocrine Carcinoma)

**Phase:** III

**Therapy:** infigratinib

**Locations:** Belgium, Canada, France, Germany, Italy, Netherlands, Puerto Rico, Spain, United Kingdom, United States

**US States:** AL, AZ, CA, CO, DC, FL, GA, IL, IN, LA, MA, MD, MO, NC, NE, NJ, NY, OH, OK, SC, TN, TX, UT, VA, WA, WV

**Contact:** QED Therapeutics [877-280-5655; Proof302.ct@qedtx.com]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

## FGFR3 A391E mutation (continued)

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VCCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 A391E mutation (continued)

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

## FGFR3 A391E mutation (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

## FGFR3 A391E mutation (continued)

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 KD mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 KD mutation (continued)

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea



## FGFR3 KD mutation (continued)

**NCT03297606**

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

**NCT03929965**

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

**NCT04565275**

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

**No NCT ID - see other identifier(s)**

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 KD mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 KD mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 KD mutation (continued)

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; [JNJ.CT@sylogent.com](mailto:JNJ.CT@sylogent.com)]

## FGFR3 KD mutation (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

## FGFR3 mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan



## FGFR3 mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 mutation (continued)

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; [JNJ.CT@sylogent.com](mailto:JNJ.CT@sylogent.com)]

## FGFR3 mutation (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 V555 mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 V555 mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

## FGFR3 V555 mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 V555 mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## FGFR3 V555 mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 V555 mutation (continued)

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; [JNJ.CT@sylogent.com](mailto:JNJ.CT@sylogent.com)]

## FGFR3 V555 mutation (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 V557 mutation

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03210714

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** APEC1621B, NCI-2017-01159, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** Aggressive, FGFR, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** EPOC 1805, JapicCTI-194624, JapicCTI-194796, TIFFANY

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** futibatinib

**Location:** Japan

## FGFR3 V557 mutation (continued)

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT02691793

Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** 2016-02-098

**Population segments:** (N/A), FGFR, Second line

**Phase:** II

**Therapy:** sunitinib

**Location:** Republic of Korea

## FGFR3 V557 mutation (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT03929965

Anlotinib in Advanced Solid Tumors With FGFR Alteration

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR mutation

**Other identifier:** ASTFA

**Population segments:** Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 V557 mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 mutation

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 V557 mutation (continued)

### NCT04294277

Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** EAU RF 2018-02, EAURF2018-02, EudraCT Number: 2017-004426-15, EudraCT Number: 2019-001833-14, PEGASUS

**Population segments:** Adjuvant, FGFR, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 mutation

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Bladder Cancer, Solid Tumor

**Variant class:** FGFR3 mutation

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04172675

A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR mutation

**Other identifiers:** 42756493BLC2003, 42756493BLC2003, CR108699, CTR20201841, CTRI/2021/08/036009, EudraCT Number: 2019-002449-39, JapicCTI-205145, NCI-2020-00674, RG1121102

**Population segments:** FGFR, Maintenance/Consolidation, Second line, Stage 0

**Phase:** II

**Therapy:** erdafitinib

**Locations:** Argentina, Australia, Belgium, Brazil, China, Czech Republic, France, Germany, Italy, Japan, Poland, Republic of Korea, Spain, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, FL, GA, IL, KS, NC, NY, OH, PA, TN, TX, WA, WI

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]



## FGFR3 V557 mutation (continued)

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04004975

Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma

**Cancer type:** Glioblastoma

**Variant class:** FGFR mutation

**Other identifier:** ShandongCHI006

**Population segments:** (N/A), FGFR, Second line

**Phase:** I/II

**Therapy:** anlotinib hydrochloride

**Location:** China

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; [JNJ.CT@sylogent.com](mailto:JNJ.CT@sylogent.com)]

## FGFR3 V557 mutation (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## FGFR3 amplification

### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 amplification

**Other identifiers:** 20170529, NCI-2017-00510, Pro00014171, TAPUR

**Population segments:** Aggressive, BRAF, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), FGFR, First line, Follicular lymphoma (FL), Fourth line or greater, Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Third line, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** United States

**US States:** AL, AZ, CA, FL, GA, HI, IL, IN, ME, MI, NC, ND, NE, NH, OH, OR, PA, SD, TX, UT, VA, WA

**Contact:** Pam Mangat [pam.mangat@asco.org]

### NCT04233567

A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR amplification

**Other identifiers:** NCI-2019-06869, OSU-19041

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** infigratinib

**Location:** United States

**US State:** OH

**Contact:** The Ohio State University Comprehensive Cancer Center [800-293-5066; OSUCCCClinicaltrials@osumc.edu]

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

## FGFR3 amplification (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

## FGFR3 amplification (continued)

### NCT04936295

A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 amplification

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** SYSU005

**Population segments:** Estrogen receptor positive, FGFR, First line, HER2 negative, HER2 positive, Progesterone receptor positive, Stage IV

**Phase:** II

**Therapies:** hormone therapy, anlotinib hydrochloride

**Location:** China

### NCT04096417

A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations

**Cancer type:** Colorectal Cancer

**Variant class:** FGFR3 amplification

**Other identifiers:** ACCRU-GI-1701, NCI-2019-05877, VICCGI2028

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** United States

**US States:** AZ, GA, MN, NC, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04077255

Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications

**Cancer type:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Variant class:** FGFR3 amplification

**Other identifiers:** 31973, KCT0004314, NCC2019-0196

**Population segments:** EGFR, FGFR, Second line, Stage IV

**Phase:** II

**Therapies:** rogaratinib, chemotherapy

**Location:** Republic of Korea

### NCT04483505

Rogatinib, Palbociclib and Fulvestrant in Advanced Hormone Receptor Positive, FGFR1/2/3-positive Breast Cancer: Phase I Clinical Trial Plus an Expansion Cohort

**Cancer type:** Breast Cancer

**Variant class:** FGFR3 amplification

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** EudraCT Number: 2020-000055-12, ROGABREAST

**Population segments:** Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** rogaratinib, palbociclib, hormone therapy

**Location:** Spain

## FGFR3 amplification (continued)

### NCT03827850

A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.

**Cancer type:** Non-Small Cell Lung Cancer

**Variant class:** FGFR activating aberration

**Other identifiers:** EudraCT Number: 2018-000399-13, FIND, FIND Trial, Uni-Koeln-3254

**Population segments:** FGFR, Second line, Squamous Cell, Stage III, Stage IV

**Exclusion criteria variant classes:** ALK aberration (Non-Small Cell Lung Cancer), BRAF aberration (Non-Small Cell Lung Cancer), EGFR aberration (Non-Small Cell Lung Cancer), NTRK aberration (Non-Small Cell Lung Cancer), ROS1 aberration (Non-Small Cell Lung Cancer)

**Phase:** II

**Therapy:** erdafitinib

**Location:** Germany

### NCT02150967

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.

**Cancer type:** Cholangiocarcinoma

**Variant class:** FGFR activating aberration

**Other identifiers:** 14-183, 14-2200, 14-328, 15452, 2014-0372, 2014-081, CBGJ398X2204, EudraCT Number: 2013-005085-19, NCI-2014-01310, REec-2014-1022, Trial 3GB-14-1

**Population segments:** FGFR, Fourth line or greater, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapy:** infigratinib

**Locations:** Belgium, Germany, Singapore, Spain, Thailand, United Kingdom, United States

**US States:** CA, MA, MI, NY, OH, TX

**Contact:** QED Therapeutics [877-280-5655; clinicaltrials@QEDTx.com]

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## FGFR3 amplification (continued)

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; clinicaltrialinfo@taihooncology.com]

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

## FGFR3 amplification (continued)

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

**No NCT ID - see other identifier(s)**  
Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]



## FGFR3 aberration

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** pemigatinib

**Location:** Italy

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR3 aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** sunitinib

**Location:** Canada

### NCT04565275

A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.

**Cancer type:** Bladder Urothelial Carcinoma, Cholangiocarcinoma, Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** ICP-CL-00303

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapy:** ICP-192

**Location:** United States

**US States:** AZ, CO, FL, MN

**Contact:** Olivia Yang [609-524-0684; olivia.yang@INNOCAREPHARMA.COM]

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## FGFR3 aberration (continued)

### No NCT ID - see other identifier(s)

A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** FGFR aberration

**Other identifier:** JapicCTI-195063

**Population segments:** FGFR, Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** futibatinib, pembrolizumab

**Location:** Japan

### NCT04595747

Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)

**Cancer type:** Soft Tissue Sarcoma

**Variant class:** FGFR3 aberration

**Other identifiers:** 10411, NCI-2020-08011

**Population segments:** FGFR, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** rogaratinib

**Location:** United States

**US States:** CA, MA, MD, NY

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04149691

A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies

**Cancer type:** Bladder Cancer, Gastric Cancer, Non-Small Cell Lung Cancer

**Variant class:** FGFR3 aberration

**Other identifier:** 01FGFR2018

**Population segments:** FGFR, Line of therapy N/A, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapy:** CPL-304-110

**Location:** Poland

### NCT04601857

A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** EudraCT Number: 2020-000945-15, TAS-120-203

**Population segments:** FGFR, First line, Stage III, Stage IV

**Phase:** II

**Therapies:** futibatinib, pembrolizumab

**Location:** United States

**US State:** MI

**Contact:** Dr. Maciej Gil [609-250-7336; [clinicaltrialinfo@taihooncology.com](mailto:clinicaltrialinfo@taihooncology.com)]

## FGFR3 aberration (continued)

### NCT03473743

A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer

**Cancer type:** Bladder Urothelial Carcinoma

**Variant class:** FGFR aberration

**Other identifiers:** 17165, 2018-0142, 42756493BLC2002, CR108445, EudraCT Number: 2017-001980-19, NCI-2018-00997, NORSE, USO 17165, USOR 17165

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Stage IV, Third line

**Phase:** I/II

**Therapies:** erdafitinib, cetrelimab

**Locations:** Belarus, Belgium, Brazil, France, Italy, Poland, Republic of Korea, Russian Federation, Spain, Taiwan, Turkey, United Kingdom, United States

**US States:** CO, MD, NC, NY, PA, TX, VA

**Contact:** Study Contact [844-434-4210; JNJ.CT@sylogent.com]

### NCT02393248

A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)

**Cancer type:** Bladder Urothelial Carcinoma, Breast Cancer, Cholangiocarcinoma, Endometrial Carcinoma, Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, FIGHT-101, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

**Population segments:** FGFR, First line, Fourth line or greater, Second line, Squamous Cell, Stage III, Stage IV, Third line

**Phase:** I/II

**Therapies:** pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab

**Location:** United States

**US States:** FL, NJ, TX

**Contact:** Incyte Call Center [855-463-3463]

### No NCT ID - see other identifier(s)

Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors

**Cancer type:** Solid Tumor

**Variant class:** FGFR aberration

**Other identifiers:** BTP-26811, CTR20192140

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** BPI-17509

**Location:** China

## FGFR3 aberration (continued)

### NCT04572295

An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** E7090-J081-102, JapicCTI-205429

**Population segments:** Estrogen receptor positive, HER2 negative, Second line, Stage IV

**Phase:** I

**Therapies:** E-7090, hormone therapy

**Location:** Japan

### NCT04504331

A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** FGFR aberration

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** BRS0113, K08CA252457

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I

**Therapies:** infigratinib, hormone therapy

**Location:** United States

**US State:** CA

**Contact:** Allison K. Zhang [650-736-5790; axkong@stanford.edu]

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 G370C mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3 R248C mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3 S249C mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>erdafitinib</b> <sup>1</sup>	35
<i>FGFR3-TACC3 fusion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>erdafitinib</b> <sup>1</sup>	31
<i>FGFR3-BAIAP2L1 fusion</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>erdafitinib</b> <sup>1</sup>	30

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 Y373C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	29
<i>FGFR3 K650E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	33
<i>FGFR3 K650M mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650Q mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650T mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 activating mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 K652E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 fusion</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	27
<i>FGFR3 A391E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	26
<i>FGFR3 KD mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V555 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V557 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 amplification</i> Prognostic significance: None Diagnostic significance: None	None	None	21
<i>FGFR3 aberration</i> Prognostic significance: None Diagnostic significance: None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

● In this cancer type
○ In other cancer type
◐ In this cancer type and other cancer types
✕ No evidence

### FGFR3 G370C mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	◐ (II)
infigratinib	✕	✕	✕	✕	◐ (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	◐ (II)
ICP-192	✕	✕	✕	✕	◐ (II)
pemigatinib	✕	✕	✕	✕	◐ (II)
anlotinib hydrochloride	✕	✕	✕	✕	◐ (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 G370C mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 R248C mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	● (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 S249C mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	● (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3-TACC3 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	○ (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3-TACC3 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
pemigatinib	✕	✕	✕	✕	ⓘ (II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I)
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3-BAIAP2L1 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	○ (II)
infigratinib	✕	✕	✕	✕	ⓘ (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
ICP-192	✕	✕	✕	✕	ⓘ (II)
pemigatinib	✕	✕	✕	✕	ⓘ (II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3-BAIAP2L1 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 Y373C mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	○	○	✕	○	ⓘ (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
ICP-192	✕	✕	✕	✕	ⓘ (II)
pemigatinib	✕	✕	✕	✕	ⓘ (II)
anlotinib hydrochloride	✕	✕	✕	✕	ⓘ (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
erdafitinib, pembrolizumab	✕	✕	✕	✕	○ (III)
infigratinib	✕	✕	✕	✕	○ (III)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 Y373C mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 K650E mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	ⓘ (II)
infigratinib	✕	✕	✕	✕	ⓘ (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
pemigatinib	✕	✕	✕	✕	ⓘ (II)
anlotinib hydrochloride	✕	✕	✕	✕	ⓘ (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 K650M mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 K650Q mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 K650Q mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 K650T mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 K650T mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 activating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
infigratinib	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 activating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 K652E mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
infigratinib	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	○ (II)
infigratinib	✕	✕	✕	✕	● (III)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
derazantinib, atezolizumab	✕	✕	✕	✕	○ (I/II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 A391E mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 A391E mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
infigratinib	✕	✕	✕	✕	○ (III)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 KD mutation





Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



















## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### FGFR3 KD mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
BPI-17509	×	×	×	×	 (I)
CPL-304-110	×	×	×	×	 (I)
E-7090, hormone therapy	×	×	×	×	 (I)
infigratinib, hormone therapy	×	×	×	×	 (I)

### FGFR3 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	×	×	×	 (II)	 (II)
futibatinib, pembrolizumab	×	×	×	×	 (II)
pemigatinib	×	×	×	×	 (II)
anlotinib hydrochloride	×	×	×	×	 (I/II)
futibatinib	×	×	×	×	 (II)
sunitinib	×	×	×	×	 (II)
ICP-192	×	×	×	×	 (I/II)
TAS-117, futibatinib	×	×	×	×	 (I/II)
durvalumab, olaparib, hormone therapy	×	×	×	×	 (II)
rogaratinib	×	×	×	×	 (II)
rogaratinib, chemotherapy	×	×	×	×	 (II)
erdafitinib, cetrelimab	×	×	×	×	 (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	×	×	×	×	 (I/II)
BPI-17509	×	×	×	×	 (I)
CPL-304-110	×	×	×	×	 (I)
E-7090, hormone therapy	×	×	×	×	 (I)
infigratinib, hormone therapy	×	×	×	×	 (I)

### FGFR3 V555 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	×	×	×	 (II)	 (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 V555 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 V557 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
erdafitinib	✕	✕	✕	○	● (II)
futibatinib, pembrolizumab	✕	✕	✕	✕	● (II)
pemigatinib	✕	✕	✕	✕	● (II)
anlotinib hydrochloride	✕	✕	✕	✕	● (I/II)
futibatinib	✕	✕	✕	✕	● (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 ✕ No evidence

### FGFR3 V557 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)

### FGFR3 amplification













Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
futibatinib, pembrolizumab	✕	✕	✕	✕	ⓘ (II)
infigratinib	✕	✕	✕	✕	ⓘ (II)
pemigatinib	✕	✕	✕	✕	ⓘ (II)
sunitinib	✕	✕	✕	✕	● (II)
ICP-192	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
erdafitinib	✕	✕	✕	✕	○ (II)
hormone therapy, anlotinib hydrochloride	✕	✕	✕	✕	○ (II)
rogaratinib	✕	✕	✕	✕	○ (II)
rogaratinib, chemotherapy	✕	✕	✕	✕	○ (II)
erdafitinib, cetrelimab	✕	✕	✕	✕	○ (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	✕	✕	✕	✕	○ (I/II)
BPI-17509	✕	✕	✕	✕	○ (I)
CPL-304-110	✕	✕	✕	✕	○ (I)
E-7090, hormone therapy	✕	✕	✕	✕	○ (I)
infigratinib, hormone therapy	✕	✕	✕	✕	○ (I)
rogaratinib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type
  In other cancer type
  In this cancer type and other cancer types
  No evidence

### FGFR3 aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
futibatinib, pembrolizumab	×	×	×	×	 (II)
pemigatinib	×	×	×	×	 (II)
sunitinib	×	×	×	×	 (II)
ICP-192	×	×	×	×	 (I/II)
TAS-117, futibatinib	×	×	×	×	 (I/II)
rogaratinib	×	×	×	×	 (II)
erdafitinib, cetrelimab	×	×	×	×	 (I/II)
pemigatinib, pembrolizumab, trastuzumab, chemotherapy, retifanlimab	×	×	×	×	 (I/II)
BPI-17509	×	×	×	×	 (I)
CPL-304-110	×	×	×	×	 (I)
E-7090, hormone therapy	×	×	×	×	 (I)
infigratinib, hormone therapy	×	×	×	×	 (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>FGFR3 G370C mutation</b> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<b>FGFR3 R248C mutation</b> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<b>FGFR3 S249C mutation</b> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	35
<b>FGFR3-TACC3 fusion</b> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	31
<b>FGFR3-BAIAP2L1 fusion</b> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	30

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 Y373C mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>erdafitinib</b> <sup>1</sup>	29
<i>FGFR3 K650E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	33
<i>FGFR3 K650M mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650Q mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 K650T mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	32
<i>FGFR3 activating mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 K652E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	31
<i>FGFR3 fusion</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	27
<i>FGFR3 A391E mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	26
<i>FGFR3 KD mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V555 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25
<i>FGFR3 V557 mutation</i> Prognostic significance: None Diagnostic significance: None	None	erdafitinib	25

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>FGFR3 amplification</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	21
<i>FGFR3 aberration</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	13

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### FGFR3 G370C mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III

## Clinical Trials Summary (continued)

### FGFR3 G370C mutation (continued)

NCT ID	Title	Phase
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II



## Clinical Trials Summary (continued)

### FGFR3 G370C mutation (continued)

NCT ID	Title	Phase
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 R248C mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II

## Clinical Trials Summary (continued)

### FGFR3 R248C mutation (continued)

NCT ID	Title	Phase
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

## Clinical Trials Summary (continued)

### FGFR3 S249C mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II

## Clinical Trials Summary (continued)

### FGFR3 S249C mutation (continued)

NCT ID	Title	Phase
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3-TACC3 fusion

NCT ID	Title	Phase
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04189445	A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II

## Clinical Trials Summary (continued)

### FGFR3-TACC3 fusion (continued)

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II
NCT04424966	A Phase 0 Study of Infigratinib in Recurrent High-Grade Glioma Participants Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration With PK Triggered Expansion Cohort	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II

## Clinical Trials Summary (continued)

### FGFR3-TACC3 fusion (continued)

NCT ID	Title	Phase
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3-BAIAP2L1 fusion

NCT ID	Title	Phase
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04189445	A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I



## Clinical Trials Summary (continued)

### FGFR3-BAIAP2L1 fusion (continued)

NCT ID	Title	Phase
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II

## Clinical Trials Summary (continued)

### FGFR3-BAIAP2L1 fusion (continued)

NCT ID	Title	Phase
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 Y373C mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT03390504	A Phase III Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects With Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	III
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT02365597	A Phase II, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects With Metastatic or Surgically Unresectable Urothelial Cancer With FGFR Genomic Alterations.	II
NCT04492293	A Phase II, Multicenter, Single Arm, Open-label Study of ICP-192 in Subjects with Surgically Unresectable or Metastatic Bladder Urothelial Cancer with FGFR Genetic Aberrations.	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II



## Clinical Trials Summary (continued)

### FGFR3 Y373C mutation (continued)

NCT ID	Title	Phase
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 K650E mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II

## Clinical Trials Summary (continued)

### FGFR3 K650E mutation (continued)

NCT ID	Title	Phase
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04424966	A Phase 0 Study of Infigratinib in Recurrent High-Grade Glioma Participants Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration With PK Triggered Expansion Cohort	I
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II

## Clinical Trials Summary (continued)

### FGFR3 K650E mutation (continued)

NCT ID	Title	Phase
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 K650M mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I

## Clinical Trials Summary (continued)

### FGFR3 K650M mutation (continued)

NCT ID	Title	Phase
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I

## Clinical Trials Summary (continued)

### FGFR3 K650M mutation (continued)

NCT ID	Title	Phase
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 K650Q mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II

## Clinical Trials Summary (continued)

### FGFR3 K650Q mutation (continued)

NCT ID	Title	Phase
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 K650T mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II



## Clinical Trials Summary (continued)

### FGFR3 K650T mutation (continued)

NCT ID	Title	Phase
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II

## Clinical Trials Summary (continued)

### FGFR3 K650T mutation (continued)

NCT ID	Title	Phase
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 activating mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II



## Clinical Trials Summary (continued)

### FGFR3 activating mutation (continued)

NCT ID	Title	Phase
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

## Clinical Trials Summary (continued)

### FGFR3 K652E mutation

NCT ID	Title	Phase
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II

## Clinical Trials Summary (continued)

### FGFR3 K652E mutation (continued)

NCT ID	Title	Phase
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 fusion

NCT ID	Title	Phase
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT04189445	A Phase II Study of Futibatinib in Patients With Specific FGFR Aberrations	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT05019794	A Phase IIa of Infigratinib in Subjects With Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma With FGFR2 Amplification or Other Advanced Solid Tumors With Other FGFR Alterations	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II

## Clinical Trials Summary (continued)

### FGFR3 fusion (continued)

NCT ID	Title	Phase
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
NCT04045613	An Open-label Multi-cohort Phase Ib/II Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations.	I/II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

## Clinical Trials Summary (continued)

### FGFR3 A391E mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04197986	Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects With Invasive Urothelial Carcinoma With Susceptible FGFR3 Genetic Alterations (PROOF 302).	III
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II

## Clinical Trials Summary (continued)

### FGFR3 A391E mutation (continued)

NCT ID	Title	Phase
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 KD mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II



## Clinical Trials Summary (continued)

### FGFR3 KD mutation (continued)

NCT ID	Title	Phase
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II

## Clinical Trials Summary (continued)

### FGFR3 mutation (continued)

NCT ID	Title	Phase
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 V555 mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II



## Clinical Trials Summary (continued)

### FGFR3 V555 mutation (continued)

NCT ID	Title	Phase
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I

## Clinical Trials Summary (continued)

### FGFR3 V555 mutation (continued)

NCT ID	Title	Phase
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 V557 mutation

NCT ID	Title	Phase
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03210714	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase II Subprotocol of JNJ-42756493 (Erdafitinib) in Patients With Tumors Harboring FGFR 1/2/3/4 Alterations	II
No NCT ID	A Multicenter Phase II Basket-type Clinical Trial to Evaluate Efficacy and Safety of TAS-120 in Patients with Advanced Solid Malignancies with FGFR Alterations in Circulating Tumor DNA	II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT02691793	Study to Evaluate the Safety and Efficacy of Sunitinib, in Subject With Refractory Solid Tumors	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT03929965	Anlotinib in Advanced Solid Tumors With FGFR Alteration	I
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04294277	Open-label, Single-arm, Phase II Study, Evaluating Safety and Efficacy of INCB054828 (Pemigatinib) as Adjuvant Therapy for Molecularly-selected, High-risk Patients With Urothelial Carcinoma Who Have Received Radical Surgery	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04172675	A Randomized Phase II Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions	II

## Clinical Trials Summary (continued)

### FGFR3 V557 mutation (continued)

NCT ID	Title	Phase
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04004975	Phase II Clinical Trials on Anlotinib for the Treatment of Recurrent Glioblastoma	I/II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 amplification

NCT ID	Title	Phase
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04233567	A Phase II Study of Oral Infigratinib in Adult Patients With Advanced or Metastatic Solid Tumors With FGFR1-3 Gene Fusions or Other FGFR Genetic Alterations	II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04936295	A Phase II Study of the Efficacy and Tolerability of Fulvestrant Plus Anlotinib in HR(+)/HER2(-) Metastatic Breast Cancer Patients With FGFR Mutation	II
NCT04096417	A Phase II, Multicenter, Single-Arm Study of Pemigatinib in Patients With Metastatic or Unresectable Colorectal Cancer Harboring FGFR Alterations	II
NCT04077255	Anti-EGFR Antibody (GC-1118) in Combination With Weekly Paclitaxel as a Second-line Therapy for Gastric and Gastroesophageal Junction Adenocarcinomas With Amplifications	II
NCT04483505	Rogaratinib, Palbociclib and Fulvestrant in Advanced Hormone Receptor Positive, FGFR1/2/3-positive Breast Cancer: Phase I Clinical Trial Plus an Expansion Cohort	I
NCT03827850	A Phase II Trial to Evaluate Efficacy and Safety of Erdafitinib in Patients With Advanced Squamous Non Small Cell Lung Carcinoma (sqNSCLC) Harboring Fibroblast Growth Factor Receptor (FGFR) Genetic Alterations After Relapse of Standard Therapy.	II

## Clinical Trials Summary (continued)

### FGFR3 amplification (continued)

NCT ID	Title	Phase
NCT02150967	A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations who Failed or are Intolerant to Platinum-based Chemotherapy.	II
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

### FGFR3 aberration

NCT ID	Title	Phase
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
NCT04565275	A Multi-center Open-label, Phase I/II Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ICP-192 in Patients With Advanced Solid Tumors and FGFR Gene Alterations.	I/II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
No NCT ID	A Phase Ib Study to Assess the Safety, Tolerability, and Efficacy of TAS-120 (Futibatinib) in Combination with MK-3475 (Pembrolizumab) in Patients with Solid Tumors.	I
NCT04595747	Phase II Study of Rogaratinib (BAY 1163877) in the Treatment of Patients With Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST)	II
NCT04149691	A Phase I, Open-label, Multicentre, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of Oral CPL304110, in Adult Subjects With Advanced Solid Malignancies	I
NCT04601857	A Phase II Study Evaluating Futibatinib (TAS 120) Plus Pembrolizumab in the Treatment of Advanced or Metastatic Urothelial Carcinoma	II
NCT03473743	A Phase Ib-II Study to Evaluate Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Various Regimens of Erdafitinib in Subjects With Metastatic or Locally Advanced Urothelial Cancer	I/II

## Clinical Trials Summary (continued)

### FGFR3 aberration (continued)

NCT ID	Title	Phase
NCT02393248	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies - (FIGHT-101)	I/II
No NCT ID	Phase I Clinical Study of BPI-17509 In Patients With Advanced Solid Tumors	I
NCT04572295	An Open-label Phase Ib Study of E7090 Monotherapy and in Combination With Other Anticancer Agents in Subjects With ER+, HER2- Recurrent/Metastatic Breast Cancer	I
NCT04504331	A Phase IB Study of Infigratinib in Combination With Tamoxifen in Hormone Receptor Positive, HER2 Negative, FGFR Altered Advanced Breast Cancer	I

## Sample Cancer Type: Unknown Primary Origin

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### Report Highlights

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## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA E542K mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<i>PIK3CA E545K mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<i>PIK3CA H1047L mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<i>PIK3CA H1047R mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<i>PIK3CA H1047Y mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	36
<i>PIK3CA E545A mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	33
<i>PIK3CA E545D [c.1635G&gt;T]</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	33
<i>PIK3CA E545G mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	33
<i>PIK3CA Q546E mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	31
<i>PIK3CA Q546R mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	31

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA C420R mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	31
<i>PIK3CA H1047 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	36
<i>PIK3CA activating mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	34
<i>PIK3CA E545 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	33
<i>PIK3CA E542 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	32
<i>PIK3CA exon 20 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	31
<i>PIK3CA exon 9 mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	alpelisib + hormone therapy	31
<i>PIK3CA mutation</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	31
<i>PIK3CA mutation status</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	14
<i>PIK3CA amplification</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	12
<i>PIK3CA aberration</i> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

FDA information is current as of 2021-10-13. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

#### PIK3CA E542K mutation

##### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA E542K mutation

Other criteria: ERBB2 negative, Hormone receptor positive

##### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

##### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

#### PIK3CA E545K mutation

##### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA E545K mutation

Other criteria: ERBB2 negative, Hormone receptor positive

##### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

##### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

#### PIK3CA H1047L mutation

##### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA H1047L mutation

Other criteria: ERBB2 negative, Hormone receptor positive

##### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

##### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)



## PIK3CA H1047R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA H1047R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA H1047Y mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA H1047Y mutation

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA E545A mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA E545A mutation

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA E545D [c.1635G>T]

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA E545D [c.1635G>T]

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA E545G mutation

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA E545G mutation

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA Q546E mutation

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA Q546E mutation

Other criteria: ERBB2 negative, Hormone receptor positive

#### Indications and usage:

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA Q546R mutation

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA Q546R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

**Indications and usage:**

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## PIK3CA C420R mutation

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-07-20

Variant class: PIK3CA C420R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

**Indications and usage:**

PIQRAY® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212526Orig1s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212526Orig1s004lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2021-10-01. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### PIK3CA E542K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

### PIK3CA E545K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

### PIK3CA H1047L mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

## PIK3CA H1047R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

## PIK3CA H1047Y mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

## PIK3CA H1047 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

## PIK3CA activating mutation

### ○ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA activating mutation

Other criteria: ERBB2 negative, Hormone receptor positive

NCCN Recommendation category: 1

Population segment (Line of therapy):

- Stage IV; Invasive, Recurrent, Unresectable, Local, Regional (Second-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 8.2021]

## Current EMA Information

- ☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

EMA information is current as of 2021-10-13. For the most up-to-date information, search [www.ema.europa.eu/ema](https://www.ema.europa.eu/ema).

### PIK3CA E542K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA E542K mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

### PIK3CA E545K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA E545K mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

### PIK3CA H1047L mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA H1047L mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

### PIK3CA H1047R mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA H1047R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA H1047Y mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA H1047Y mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA E545A mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA E545A mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA E545D [c.1635G>T]

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA E545D [c.1635G>T]

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA E545G mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA E545G mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)



## PIK3CA Q546E mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA Q546E mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA Q546R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA Q546R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## PIK3CA C420R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Label as of: 2021-10-11

Variant class: PIK3CA C420R mutation

Other criteria: ERBB2 negative, Hormone receptor positive

Reference:

[https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/piqray-epar-product-information_en.pdf)

## Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2021-10-01. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### PIK3CA E542K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

### PIK3CA E545K mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

### PIK3CA H1047L mutation

#### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 20 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA H1047R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 20 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA H1047Y mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 20 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA E545A mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA E545D [c.1635G>T]

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA E545G mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA Q546E mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA Q546R mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA H1047 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 20 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA E545 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA E542 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA exon 20 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 20 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## PIK3CA exon 9 mutation

### ☐ alpelisib + fulvestrant

Cancer type: Breast Cancer

Variant class: PIK3CA exon 9 mutation

Other criteria: ERBB2 negative, ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):

- Luminal A, Luminal B; Advanced (Line of therapy not specified); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Annals of Oncology (2020), doi: <https://doi.org/10.1016/j.annonc.2020.09.010> (ABC 5)]

## Current Clinical Trials Information

Clinical Trials information is current as of 2021-10-01. For the most up-to-date information regarding a particular trial, search [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

### PIK3CA E542K mutation

#### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E542K mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

#### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E542 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

#### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

## PIK3CA E542K mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## PIK3CA E542K mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA E542K mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA E542K mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA E542K mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** ACTRN12619001117101, BCT 1901, BCT 1901 (CAPTURE), CAPTURE

**Population segments:** Estrogen receptor positive, HER2 negative, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Australia

## PIK3CA E542K mutation (continued)

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; sdamodaran@mdanderson.org]

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

## PIK3CA E542K mutation (continued)

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

## PIK3CA E542K mutation (continued)

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

## PIK3CA E542K mutation (continued)

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

## PIK3CA E542K mutation (continued)

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea



## PIK3CA E542K mutation (continued)

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## PIK3CA E542K mutation (continued)

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA E545K mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545K mutation (continued)

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

## PIK3CA E545K mutation (continued)

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA E545K mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; [Geoffrey\\_S Shapiro@dfci.harvard.edu](mailto:Geoffrey_S Shapiro@dfci.harvard.edu)]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; [yangt@mskcc.org](mailto:yangt@mskcc.org)]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

## PIK3CA E545K mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545K mutation (continued)

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA E545K mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** ACTRN12619001117101, BCT 1901, BCT 1901 (CAPTURE), CAPTURE

**Population segments:** Estrogen receptor positive, HER2 negative, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Australia

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; [sdamodaran@mdanderson.org](mailto:sdamodaran@mdanderson.org)]

## PIK3CA E545K mutation (continued)

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]



**PIK3CA E545K mutation (continued)****NCT04524000**

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

**NCT04544189**

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

**NCT04762979**

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA E545K mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

## PIK3CA E545K mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

## PIK3CA E545K mutation (continued)

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA E545K mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA E545K mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA H1047L mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

## PIK3CA H1047L mutation (continued)

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

## PIK3CA H1047L mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**



## PIK3CA H1047L mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA H1047L mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047L mutation (continued)

### No NCT ID - see other identifier(s)

BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA H1047L mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** ACTRN12619001117101, BCT 1901, BCT 1901 (CAPTURE), CAPTURE

**Population segments:** Estrogen receptor positive, HER2 negative, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Australia

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; sdamodaran@mdanderson.org]

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

## PIK3CA H1047L mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA H1047L mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA H1047L mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA H1047L mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047L mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]



## PIK3CA H1047L mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA H1047R mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA H1047R mutation (continued)

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047R mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA H1047R mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variation class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA H1047R mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### No NCT ID - see other identifier(s)

BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA H1047R mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** ACTRN12619001117101, BCT 1901, BCT 1901 (CAPTURE), CAPTURE

**Population segments:** Estrogen receptor positive, HER2 negative, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Australia

## PIK3CA H1047R mutation (continued)

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; sdamodaran@mdanderson.org]

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

## PIK3CA H1047R mutation (continued)

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China



## PIK3CA H1047R mutation (continued)

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

## PIK3CA H1047R mutation (continued)

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

## PIK3CA H1047R mutation (continued)

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

## PIK3CA H1047R mutation (continued)

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## PIK3CA H1047R mutation (continued)

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA H1047Y mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047Y mutation (continued)

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

## PIK3CA H1047Y mutation (continued)

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA H1047Y mutation (continued)

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; [Geoffrey\\_S Shapiro@dfci.harvard.edu](mailto:Geoffrey_S Shapiro@dfci.harvard.edu)]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; [yangt@mskcc.org](mailto:yangt@mskcc.org)]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada



## PIK3CA H1047Y mutation (continued)

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047Y mutation (continued)

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; [sdamodaran@mdanderson.org](mailto:sdamodaran@mdanderson.org)]

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; [slci1research@saint-lukes.org](mailto:slci1research@saint-lukes.org)]

## PIK3CA H1047Y mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA H1047Y mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA H1047Y mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA H1047Y mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047Y mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA H1047Y mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]



## PIK3CA E545A mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; [Global-Roche-Genentech-Trials@gene.com](mailto:Global-Roche-Genentech-Trials@gene.com)]

## PIK3CA E545A mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

## PIK3CA E545A mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA E545A mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545A mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA E545A mutation (continued)

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA E545A mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

## PIK3CA E545A mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]



## PIK3CA E545A mutation (continued)

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA E545A mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA E545A mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA E545D [c.1635G>T]

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

## PIK3CA E545D [c.1635G>T] (continued)

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545D [c.1635G>T] (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA E545D [c.1635G>T] (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA E545D [c.1635G>T] (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA E545D [c.1635G>T] (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan



## PIK3CA E545D [c.1635G>T] (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA E545D [c.1635G>T] (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA E545D [c.1635G>T] (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545D [c.1635G>T] (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA E545D [c.1635G>T] (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA E545G mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; [jason.sudia@haihepharma.com](mailto:jason.sudia@haihepharma.com)]

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; [Global-Roche-Genentech-Trials@gene.com](mailto:Global-Roche-Genentech-Trials@gene.com)]

## PIK3CA E545G mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

## PIK3CA E545G mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan



## PIK3CA E545G mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545G mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

**PIK3CA E545G mutation (continued)****NCT04524000**

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

**NCT04544189**

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

**NCT04762979**

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA E545G mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

## PIK3CA E545G mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

## PIK3CA E545G mutation (continued)

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA E545G mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA E545G mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA Q546E mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]



## PIK3CA Q546E mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

## PIK3CA Q546E mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA Q546E mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA Q546E mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA Q546E mutation (continued)

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA Q546E mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

## PIK3CA Q546E mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

**PIK3CA Q546E mutation (continued)****NCT04345913**

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04526470**

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

**NCT04395989**

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China



## PIK3CA Q546E mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA Q546E mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA Q546R mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

## PIK3CA Q546R mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

## PIK3CA Q546R mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA Q546R mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA Q546R mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA Q546R mutation (continued)

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA Q546R mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China



## PIK3CA Q546R mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

**PIK3CA Q546R mutation (continued)****NCT04345913**

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04526470**

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

**NCT04395989**

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA Q546R mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA Q546R mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA C420R mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

## PIK3CA C420R mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

## PIK3CA C420R mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA C420R mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA C420R mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]



## PIK3CA C420R mutation (continued)

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

## PIK3CA C420R mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

## PIK3CA C420R mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

**PIK3CA C420R mutation (continued)****NCT04345913**

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

**NCT04526470**

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

**NCT04395989**

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA C420R mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA C420R mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA H1047 mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA H1047 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

## PIK3CA H1047 mutation (continued)

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

## PIK3CA H1047 mutation (continued)

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**



## PIK3CA H1047 mutation (continued)

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipiro@dfci.harvard.edu]

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

## PIK3CA H1047 mutation (continued)

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA H1047 mutation (continued)

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; sdamodaran@mdanderson.org]

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

## PIK3CA H1047 mutation (continued)

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

## PIK3CA H1047 mutation (continued)

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

## PIK3CA H1047 mutation (continued)

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

## PIK3CA H1047 mutation (continued)

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

## PIK3CA H1047 mutation (continued)

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]



## PIK3CA H1047 mutation (continued)

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA activating mutation

### NCT04632992

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** ML42439, MyTACTIC

**Population segments:** ALK, EGFR, HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

**Phase:** II

**Therapies:** inavolisib, atezolizumab + ipatasertib

**Location:** United States

**US States:** AK, AZ, CA, CT, FL, LA, MD, MI, MO, MT, NE, NJ, NY, OH, OR, TN, TX, WA

**Contact:** Reference Study ID Number: ML42439 [888-662-6728; global-roche-genentech-trials@gene.com]

## PIK3CA activating mutation (continued)

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA activating mutation

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA activating mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA activating mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variation class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variation class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA activating mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04216472

A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other identifiers:** 2019-0752, NCI-2019-08495

**Population segments:** HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, chemotherapy

**Location:** United States

**US State:** TX

**Contact:** Senthilkumar Damodaran [713-792-2817; [sdamodaran@mdanderson.org](mailto:sdamodaran@mdanderson.org)]

## PIK3CA activating mutation (continued)

### NCT05025735

Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA activating mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifier:** CBYL719A0US03T

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy, dapagliflozin

**Location:** United States

**US State:** MO

**Contact:** Kelley Aldrich [816-932-2677; slci1research@saint-lukes.org]

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

**PIK3CA activating mutation (continued)****NCT04524000**

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

**NCT04544189**

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

**NCT04762979**

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]



## PIK3CA activating mutation (continued)

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China



## PIK3CA activating mutation (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

## PIK3CA activating mutation (continued)

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA activating mutation (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA activating mutation (continued)

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA E545 mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04586335

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.

**Cancer type:** Breast Cancer, Endometrial Carcinoma, Ovarian Cancer, Prostate Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA E545 mutation

**Other identifiers:** CTR20202339, CYH33-G102

**Population segments:** BRCA, Second line, Stage III, Stage IV

**Phase:** I

**Therapies:** HH-CYH33, olaparib

**Locations:** Australia, United States

**US State:** TX

**Contact:** Dr. Jason Sudia [908-380-1329; jason.sudia@haihepharma.com]

## PIK3CA E545 mutation (continued)

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545 mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA E545 mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA E545 mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom



## PIK3CA E545 mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA E545 mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA E545 mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA E545 mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E545 mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA E545 mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA E542 mutation

### NCT04317105

A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA E542 mutation

**Other identifiers:** (BACON), 10221, 2019-1046, NCI10221, NCI-2020-01917

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** copanlisib, nivolumab, ipilimumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E542 mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]



## PIK3CA E542 mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA E542 mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA E542 mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA E542 mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA E542 mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA E542 mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA E542 mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA E542 mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]



## PIK3CA exon 20 mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA exon 20 mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA exon 20 mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA exon 20 mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA exon 20 mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA exon 20 mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA exon 20 mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA exon 20 mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.



## PIK3CA exon 20 mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA exon 20 mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA exon 9 mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA exon 9 mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA exon 9 mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA exon 9 mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA exon 9 mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA exon 9 mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France



## PIK3CA exon 9 mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA exon 9 mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA exon 9 mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA exon 9 mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA mutation

### NCT03239015

Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifier:** HETIAN64

**Population segments:** (N/A), Second line

**Phase:** II

**Therapy:** everolimus

**Location:** China

### NCT04589845

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** BO41932, EudraCT Number: 2020-001847-16, TAPISTRY

**Population segments:** ALK, First line, HER2 positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** inavolisib

**Locations:** Australia, Belgium, Brazil, Canada, China, Germany, Israel, Italy, New Zealand, Poland, Portugal, Republic of Korea, Spain, Taiwan, United States

**US States:** AL, AZ, CA, DE, FL, GA, ID, IL, IN, MD, ME, MI, MN, MO, MT, NJ, NM, NV, NY, OH, PA, SC, TN, TX, WA, WI

**Contact:** Reference Study ID Number: BO41932 [888-662-6728; Global-Roche-Genentech-Trials@gene.com]

### NCT03842228

A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 10217, 19-628, NCI10217, NCI-2019-00601

**Population segments:** Line of therapy N/A, Stage III, Stage IV

**Phase:** I

**Therapies:** copanlisib, olaparib, durvalumab

**Location:** United States

**US States:** MA, TX

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA mutation (continued)

### NCT03006172

A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer

**Cancer type:** Breast Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 16-1556, 16-521, EudraCT Number: 2016-003022-17, G039374, NCI-2017-00262

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** I

**Therapy:** inavolisib

**Locations:** Canada, France, Spain, United Kingdom, United States

**US States:** MA, NY, TN

**Contact:** Reference Study ID Number: G039374 [888-662-6728; global-roche-genentech-trials@gene.com]

### No NCT ID - see other identifier(s)

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** CO42800, EudraCT number: 2020-005057-24, ISRCTN45319897

**Population segments:** Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage I, Stage II, Stage III, Stage IV

**Phase:** I

**Therapies:** inavolisib, chemotherapy, trastuzumab, pertuzumab

**Locations:** Canada, Denmark, France, Republic of Korea, Spain, United States

**US State:**

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shapiro@dfci.harvard.edu]

## PIK3CA mutation (continued)

### NCT04192981

A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA mutation

**Other identifiers:** 19-359, NCI-2019-08530

**Population segments:** (N/A), CNS mets, Line of therapy N/A

**Phase:** I

**Therapies:** paxalisib, radiation therapy

**Location:** United States

**US States:** NJ, NY

**Contact:** Dr. T. Jonathan Yang [212-639-8157; yangt@mskcc.org]

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA mutation (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom



## PIK3CA mutation (continued)

### NCT04251533

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other identifiers:** CBYL719H12301, CBYL719H12301 53027, CTR20201097, CTRI/2020/09/027887, DOH-27-012021-7110, EPIK-B3, EudraCT Number: 2019-002637-11, NCI-2020-02353, NMRR-20-236-53027

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** III

**Therapies:** alpelisib, chemotherapy

**Locations:** Australia, Austria, Brazil, Bulgaria, China, Colombia, Croatia, France, Germany, Hungary, India, Israel, Italy, Malaysia, Mexico, Norway, Peru, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States

**US States:** CA, FL, IL, IN, KS, LA, MD, MN, MO, NY, OH, TN, TX, VA, WA

**Contact:** Novartis Pharmaceuticals [888-669-6682; novartis.email@novartis.com]

### NCT04191499

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CTR20202249, EudraCT Number: 2019-002455-42, INAVO120, NCI-2020-02312, WO41554

**Population segments:** Estrogen receptor positive, First line, HER2 negative, Progesterone receptor positive, Stage III, Stage IV

**Phase:** II/III

**Therapies:** inavolisib, palbociclib, hormone therapy

**Locations:** Australia, Belgium, Canada, China, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, New Zealand, Poland, Portugal, Republic of Korea, Russian Federation, Singapore, Spain, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

**US States:** AZ, CT, FL, GA, MA, MD, NC, NY, OR, TX, WA

**Contact:** Reference Study ID Number: WO41554 [888-662-6728; global-roche-genentech-trials@gene.com]

### NCT04524000

A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C1201, JapicCTI-205438

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** Japan

## PIK3CA mutation (continued)

### NCT04544189

A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** CBYL719C2201, CTR20200953

**Population segments:** Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** China

### NCT04762979

A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, Hormone receptor positive

**Other identifiers:** 2020-1362, BTCRC-BRE19-409, NCI-2021-01727,, UW20118

**Population segments:** Estrogen receptor positive, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

**Phase:** II

**Therapies:** alpelisib, hormone therapy

**Location:** United States

**US States:** IL, PA, WI

**Contact:** Julia Beck [317-634-5842 ext 62; jbeck@hoosiercancer.org]

### NCT04053322

An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** CADUSEIME08, DOLAF, EudraCT Number: 2018-003832-57, UC-0140/1812

**Population segments:** BRCA, Estrogen receptor positive, FGFR, HER2 negative, Progesterone receptor positive, Second line, Stage III, Stage IV

**Phase:** II

**Therapies:** durvalumab, olaparib, hormone therapy

**Location:** France

## PIK3CA mutation (continued)

### NCT03834740

A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration

**Cancer type:** Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, Anaplastic Pleomorphic Xanthoastrocytoma, Diffuse Midline Glioma, Glioblastoma

**Variant class:** PIK3CA mutation

**Other identifier:** 18-500-311-70-38

**Population segments:** (N/A), Neoadjuvant, Second line

**Phase:** II

**Therapies:** everolimus, ribociclib

**Location:** United States

**US State:** AZ

**Contact:** Phase 0 Navigator [602-406-8605; research@ivybraintumorcenter.org]

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA mutation

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + hormone therapy

**Location:** China

## PIK3CA mutation (continued)

### NCT04495621

Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens

**Cancer type:** Colon Cancer, Rectal Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** BRAF wild type, KRAS wild type, NRAS wild type

**Other identifiers:** C-PRECISE-01, EudraCT Number: 2019-003727-38, MEN1611-02, NL72727.056.20

**Population segments:** Second line, Stage IV

**Phase:** I/II

**Therapies:** MEN-1611, cetuximab

**Locations:** France, Italy, Poland, Spain, United States

**US States:** CA, WA

**Contact:** Dr. Angela Capriati - Corporate Director [acapriati@menarini-ricerche.it]

### NCT04188548

EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER + Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

**Cancer type:** Breast Cancer

**Variant class:** PIK3CA mutation

**Other inclusion criteria:** ERBB2 negative, ER positive

**Other identifiers:** 17502, 20-118, EMBER, EudraCT Number: 2019-003581-41, J2J-MC-JZLA, J2J-MC-JZLA(b), jRCT2031200271

**Population segments:** Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Second line, Stage III, Stage IV, Third line

**Phase:** I

**Therapies:** hormone therapy, alpelisib

**Locations:** Australia, Belgium, France, Japan, Republic of Korea, Spain, Taiwan, United States

**US States:** AR, AZ, CA, CO, FL, GA, MA, MD, MN, MO, NC, NY, OR, PA, TN, TX, VA, VT, WA

**Contact:** Eli Lilly and Company [877-285-4559; Clinicaltrials.gov@lilly.com]

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

## PIK3CA mutation (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

## PIK3CA mutation (continued)

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA mutation status

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

## PIK3CA mutation status (continued)

### NCT03155620

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-729, 2017-0625, 20170841, APEC1621SC, COGAPEC1621, COGAPEC1621SC, N 55017 SC, NCI-2017-01251, NCI-COG Pediatric MATCH, Pediatric MATCH

**Population segments:** ALK, Aggressive, BRAF, FGFR, HRAS, Indolent, KRAS, NRAS, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03213678

NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 17-742, APEC 1621 D, APEC 1621-D, APEC1621 D, APEC1621D, NCI-2017-01249, NCI-COG Pediatric MATCH, OCR16978, Pediatric MATCH

**Population segments:** Aggressive, Indolent, Pediatric or Adolescent, Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** samotolisib

**Locations:** Puerto Rico, United States

**US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom



## PIK3CA mutation status (continued)

### NCT04345913

A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PIK3CA mutation status

**Other identifiers:** 10382, NCI-2020-02319

**Population segments:** Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

**Exclusion criteria variant class:** AKT mutation (Triple Negative Breast Cancer)

**Phase:** I/II

**Therapies:** copanlisib, chemotherapy

**Location:** United States

**US States:** FL, MO, NY, OK, TN

**Contact:** Multiple contacts: See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for complete list of contacts.

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR mutation

**Other inclusion criteria:** AR overexpression, ERBB2 activating mutation negative

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

## PIK3CA mutation status (continued)

### NCT03994796

Genomically-Guided Treatment Trial in Brain Metastases

**Cancer type:** Central Nervous System Neoplasm

**Variant class:** PI3K/AKT/MTOR mutation

**Other identifiers:** 19102303, 19-553, A071701, Alliance A071701, Alliance-A071701, CTSU/A071701, NCI-2019-00744, PCRC\_A071701

**Population segments:** BRAF, CNS mets, Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** paxalisib

**Location:** United States

**US States:** AK, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NY, OH, OK, OR, PA, TX, UT, VA, VT, WA, WI, WY

**Contact:** Dr. Priscilla Brastianos [617-724-1074; pbrastianos@partners.org]

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

## PIK3CA mutation status (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA amplification

### NCT03065062

Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors

**Cancer type:** Endometrial Carcinoma, Head and Neck Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PIK3CA amplification

**Other identifiers:** 16-499, NCI-2017-00434

**Population segments:** Second line, Squamous Cell, Stage III, Stage IV

**Phase:** I

**Therapies:** palbociclib, gedatolisib

**Location:** United States

**US State:** MA

**Contact:** Dr. Geoffrey Shapiro [617-632-4942; Geoffrey\_Shipro@dfci.harvard.edu]

## PIK3CA amplification (continued)

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA amplification (continued)

### NCT04836663

A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors

**Cancer type:** Cervical Cancer, Endometrial Carcinoma, Ovarian Cancer

**Variant class:** PIK3CA amplification

**Other identifier:** TQ-B3525-II-03

**Population segments:** Second line, Stage III, Stage IV

**Phase:** II

**Therapy:** TQ-B3525

**Location:** China

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

## PIK3CA amplification (continued)

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## PIK3CA aberration

### NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifiers:** CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

**Population segments:** Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

**Phase:** II

**Therapy:** temsirolimus

**Location:** Canada

### No NCT ID - see other identifier(s)

Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PIK3CA aberration

**Other identifier:** JapicCTI-194864

**Population segments:** FGFR, First line, Squamous Cell, Stage III, Stage IV

**Phase:** I/II

**Therapies:** TAS-117, futibatinib

**Location:** Japan

### NCT04591431

The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy

**Cancer type:** Biliary Tract Carcinoma, Breast Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Gastroesophageal Junction Adenocarcinoma, Hepatocellular Carcinoma, Liver Cancer, Non-Small Cell Lung Cancer, Pancreatic Cancer, Unspecified Solid Tumor

**Variant class:** PI3K aberration

**Other identifiers:** EudraCT Number: 2018-002190-21, MAR-BAS-18-005, ROME

**Population segments:** Second line, Stage IV

**Phase:** II

**Therapy:** ipatasertib

**Location:** Italy

### NCT03673787

Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** CCR4720, EudraCT Number: 2017-003005-18, IceCAP, Ice-CAP, IRAS ID 233461

**Population segments:** Hormone refractory, Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** ipatasertib, atezolizumab

**Location:** United Kingdom

## PIK3CA aberration (continued)

### NCT04526470

Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer

**Cancer type:** Gastric Cancer

**Variant class:** PIK3CA aberration

**Other identifiers:** B-2004/604-002, KCT0005467

**Population segments:** Second line, Stage III, Stage IV

**Phase:** I/II

**Therapies:** alpelisib, chemotherapy

**Location:** Republic of Korea

### NCT04395989

An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** (FUTURE SUPER, FUTURE-SUPER, SCHBCC-N031

**Population segments:** HER2 negative, Line of therapy N/A, Stage III, Stage IV, Triple receptor negative

**Phase:** II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT04849364

A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** HCRN BRE18-334, PERSEVERE

**Population segments:** Adjuvant, HER2 negative, Stage I, Stage II, Stage III, Triple receptor negative

**Phase:** II

**Therapies:** inavolisib, chemotherapy

**Location:** United States

**US State:** IN

**Contact:** Dr. Bryan P. Schneider [317-948-3885; bpschnei@iu.edu]

### NCT04486352

A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer

**Cancer type:** Endometrial Carcinoma

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** AFT-50, EndoMAP

**Population segments:** (N/A), Second line, Third line

**Phase:** I/II

**Therapies:** atezolizumab, ipatasertib

**Location:** United States

**US State:** CA

**Contact:** Quality Management and Compliance [617-732-8727; ClinicalTrials.Queries@alliancefoundationtrials.org]



## PIK3CA aberration (continued)

### NCT03805399

Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping —FUSCC-TNBC-Umbrella Trial

**Cancer type:** Triple Negative Breast Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other identifiers:** 1807188-16, FUTURE

**Population segments:** HER2 negative, Second line, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** everolimus + chemotherapy

**Location:** China

### NCT04060394

A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.

**Cancer type:** Castration-Resistant Prostate Cancer

**Variant class:** PI3K/AKT/MTOR pathway

**Other inclusion criteria:** PTEN underexpression

**Other identifiers:** LAE201INT2101, NCI-2020-03668

**Population segments:** Fourth line or greater, Hormone refractory, Stage IV, Third line

**Exclusion criteria variant classes:** PI3K/AKT/MTOR pathway (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor, Prostate Well Differentiated Neuroendocrine Tumor), PI3K/AKT/MTOR pathway & PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor), PTEN deletion (Prostate Small Cell Neuroendocrine Carcinoma, Prostate Well Differentiated Neuroendocrine Tumor)

**Phase:** I/II

**Therapies:** hormone therapy, afuresertib, steroid, chemotherapy

**Location:** United States

**US States:** CA, CT, IL, KS, NY, OR, SC, TX, WA

**Contact:** Yong Yue [732-850-2641; yong.yue@laeknatp.com]

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>PIK3CA E542K mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	37
<b>PIK3CA E545K mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	37
<b>PIK3CA H1047L mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	37
<b>PIK3CA H1047R mutation</b> <b>Prognostic significance:</b> None <b>Diagnostic significance:</b> None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	37

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA H1047Y mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	36
<i>PIK3CA E545A mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	33
<i>PIK3CA E545D [c.1635G&gt;T]</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	33
<i>PIK3CA E545G mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	33
<i>PIK3CA Q546E mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	31
<i>PIK3CA Q546R mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	31
<i>PIK3CA C420R mutation</i> Prognostic significance: None Diagnostic significance: None	None	<b>alpelisib + hormone therapy</b> <sup>1, 2</sup>	31
<i>PIK3CA H1047 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	36
<i>PIK3CA activating mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	34
<i>PIK3CA E545 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	33
<i>PIK3CA E542 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	32
<i>PIK3CA exon 20 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	31
<i>PIK3CA exon 9 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	31

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA</i> mutation Prognostic significance: None Diagnostic significance: None	None	None	31
<i>PIK3CA</i> mutation status Prognostic significance: None Diagnostic significance: None	None	None	14
<i>PIK3CA</i> amplification Prognostic significance: None Diagnostic significance: None	None	None	12
<i>PIK3CA</i> aberration Prognostic significance: None Diagnostic significance: None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Therapy Summary

● In this cancer type    
 ○ In other cancer type    
 ① In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E542K mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	○	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
inavolisib, atezolizumab + ipatasertib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E542K mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
alpelisib, hormone therapy, dapagliflozin	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA E545K mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	○	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
inavolisib, atezolizumab + ipatasertib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E545K mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
alpelisib, hormone therapy, dapagliflozin	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA H1047L mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	○	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
inavolisib, atezolizumab + ipatasertib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA H1047L mutation (continued)

























































































































Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
alpelisib, hormone therapy, dapagliflozin	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA H1047R mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant					
everolimus					 (II)
inavolisib					 (II)
inavolisib, atezolizumab + ipatasertib					 (II)
ipatasertib					 (II)
samotolisib					 (II)
temsirolimus					 (II)
copanlisib, nivolumab, ipilimumab					 (I/II)
ipatasertib, atezolizumab					 (I/II)
TAS-117, futibatinib					 (I/II)
copanlisib, olaparib, durvalumab					 (I)
HH-CYH33, olaparib					 (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab					 (I)
palbociclib, gedatolisib					 (I)
paxalisib, radiation therapy					 (I)
alpelisib, chemotherapy					 (III)
inavolisib, palbociclib, hormone therapy					 (II/III)
alpelisib, hormone therapy					 (II)
alpelisib, hormone therapy, dapagliflozin					 (II)
durvalumab, olaparib, hormone therapy					 (II)
everolimus + chemotherapy					 (II)
everolimus, ribociclib					 (II)
inavolisib, chemotherapy					 (II)
paxalisib					 (II)
TQ-B3525					 (II)
atezolizumab, ipatasertib					 (I/II)
copanlisib, chemotherapy					 (I/II)
everolimus + hormone therapy					 (I/II)
hormone therapy, afuresertib, steroid, chemotherapy					 (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA H1047R mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
MEN-1611, cetuximab	×	×	×	×	○ (I/II)
hormone therapy, alpelisib	×	×	×	×	○ (I)

### PIK3CA H1047Y mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	○	○	○	×
everolimus	×	×	×	×	● (II)
inavolisib	×	×	×	×	● (II)
inavolisib, atezolizumab + ipatasertib	×	×	×	×	● (II)
ipatasertib	×	×	×	×	● (II)
samotolisib	×	×	×	×	● (II)
temsirolimus	×	×	×	×	● (II)
copanlisib, nivolumab, ipilimumab	×	×	×	×	● (I/II)
ipatasertib, atezolizumab	×	×	×	×	● (I/II)
TAS-117, futibatinib	×	×	×	×	● (I/II)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	×	×	×	×	● (I)
palbociclib, gedatolisib	×	×	×	×	● (I)
paxalisib, radiation therapy	×	×	×	×	● (I)
alpelisib, chemotherapy	×	×	×	×	○ (III)
inavolisib, palbociclib, hormone therapy	×	×	×	×	○ (II/III)
alpelisib, hormone therapy	×	×	×	×	○ (II)
alpelisib, hormone therapy, dapagliflozin	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
everolimus + chemotherapy	×	×	×	×	○ (II)
everolimus, ribociclib	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
paxalisib	×	×	×	×	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA H1047Y mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA E545A mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E545A mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA E545D [c.1635G>T]

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E545D [c.1635G>T] (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA E545G mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
HH-CYH33, olaparib	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E545G mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA Q546E mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ① In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA Q546E mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA Q546R mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ① In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA Q546R mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

### PIK3CA C420R mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	○	✕	○	✕	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA C420R mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	×	×	×	×	● (I)
palbociclib, gedatolisib	×	×	×	×	● (I)
paxalisib, radiation therapy	×	×	×	×	● (I)
alpelisib, chemotherapy	×	×	×	×	○ (III)
inavolisib, palbociclib, hormone therapy	×	×	×	×	○ (II/III)
alpelisib, hormone therapy	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
everolimus + chemotherapy	×	×	×	×	○ (II)
everolimus, ribociclib	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
paxalisib	×	×	×	×	○ (II)
TQ-B3525	×	×	×	×	○ (II)
atezolizumab, ipatasertib	×	×	×	×	○ (I/II)
copanlisib, chemotherapy	×	×	×	×	○ (I/II)
everolimus + hormone therapy	×	×	×	×	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	×	×	×	×	○ (I/II)
MEN-1611, cetuximab	×	×	×	×	○ (I/II)
hormone therapy, alpelisib	×	×	×	×	○ (I)

### PIK3CA H1047 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	×	○	×	○	×
everolimus	×	×	×	×	● (II)
inavolisib	×	×	×	×	● (II)
inavolisib, atezolizumab + ipatasertib	×	×	×	×	● (II)
ipatasertib	×	×	×	×	● (II)
samotolisib	×	×	×	×	● (II)
temsirolimus	×	×	×	×	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA H1047 mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
copanlisib, nivolumab, ipilimumab	×	×	×	×	● (I/II)
ipatasertib, atezolizumab	×	×	×	×	● (I/II)
TAS-117, futibatinib	×	×	×	×	● (I/II)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	×	×	×	×	● (I)
palbociclib, gedatolisib	×	×	×	×	● (I)
paxalisib, radiation therapy	×	×	×	×	● (I)
alpelisib, chemotherapy	×	×	×	×	○ (III)
inavolisib, palbociclib, hormone therapy	×	×	×	×	○ (II/III)
alpelisib, hormone therapy	×	×	×	×	○ (II)
alpelisib, hormone therapy, dapagliflozin	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
everolimus + chemotherapy	×	×	×	×	○ (II)
everolimus, ribociclib	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
paxalisib	×	×	×	×	○ (II)
TQ-B3525	×	×	×	×	○ (II)
atezolizumab, ipatasertib	×	×	×	×	○ (I/II)
copanlisib, chemotherapy	×	×	×	×	○ (I/II)
everolimus + hormone therapy	×	×	×	×	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	×	×	×	×	○ (I/II)
MEN-1611, cetuximab	×	×	×	×	○ (I/II)
hormone therapy, alpelisib	×	×	×	×	○ (I)

### PIK3CA activating mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	×	○	×	×	×
everolimus	×	×	×	×	● (II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.



## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA activating mutation (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
inavolisib	✕	✕	✕	✕	● (II)
inavolisib, atezolizumab + ipatasertib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
alpelisib, hormone therapy, dapagliflozin	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA E545 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	×	×	×	○	×
everolimus	×	×	×	×	● (II)
inavolisib	×	×	×	×	● (II)
ipatasertib	×	×	×	×	● (II)
samotolisib	×	×	×	×	● (II)
temsirolimus	×	×	×	×	● (II)
copanlisib, nivolumab, ipilimumab	×	×	×	×	● (I/II)
ipatasertib, atezolizumab	×	×	×	×	● (I/II)
TAS-117, futibatinib	×	×	×	×	● (I/II)
copanlisib, olaparib, durvalumab	×	×	×	×	● (I)
HH-CYH33, olaparib	×	×	×	×	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	×	×	×	×	● (I)
palbociclib, gedatolisib	×	×	×	×	● (I)
paxalisib, radiation therapy	×	×	×	×	● (I)
alpelisib, chemotherapy	×	×	×	×	○ (III)
inavolisib, palbociclib, hormone therapy	×	×	×	×	○ (II/III)
alpelisib, hormone therapy	×	×	×	×	○ (II)
durvalumab, olaparib, hormone therapy	×	×	×	×	○ (II)
everolimus + chemotherapy	×	×	×	×	○ (II)
everolimus, ribociclib	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
paxalisib	×	×	×	×	○ (II)
TQ-B3525	×	×	×	×	○ (II)
atezolizumab, ipatasertib	×	×	×	×	○ (I/II)
copanlisib, chemotherapy	×	×	×	×	○ (I/II)
everolimus + hormone therapy	×	×	×	×	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	×	×	×	×	○ (I/II)
MEN-1611, cetuximab	×	×	×	×	○ (I/II)
hormone therapy, alpelisib	×	×	×	×	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA E542 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	✕	✕	✕	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
copanlisib, nivolumab, ipilimumab	✕	✕	✕	✕	● (I/II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA exon 20 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	✕	✕	✕	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA exon 9 mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
alpelisib + fulvestrant	✕	✕	✕	○	✕
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA mutation

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
everolimus	✕	✕	✕	✕	● (II)
inavolisib	✕	✕	✕	✕	● (II)
ipatasertib	✕	✕	✕	✕	● (II)
samotolisib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
copanlisib, olaparib, durvalumab	✕	✕	✕	✕	● (I)
inavolisib, chemotherapy, trastuzumab, pertuzumab	✕	✕	✕	✕	● (I)
palbociclib, gedatolisib	✕	✕	✕	✕	● (I)
paxalisib, radiation therapy	✕	✕	✕	✕	● (I)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (III)
inavolisib, palbociclib, hormone therapy	✕	✕	✕	✕	○ (II/III)
alpelisib, hormone therapy	✕	✕	✕	✕	○ (II)
durvalumab, olaparib, hormone therapy	✕	✕	✕	✕	○ (II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
everolimus, ribociclib	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
paxalisib	✕	✕	✕	✕	○ (II)
TQ-B3525	✕	✕	✕	✕	○ (II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
copanlisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
everolimus + hormone therapy	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)
MEN-1611, cetuximab	✕	✕	✕	✕	○ (I/II)
hormone therapy, alpelisib	✕	✕	✕	✕	○ (I)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### PIK3CA mutation status

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
ipatasertib	×	×	×	×	● (II)
samotolisib	×	×	×	×	● (II)
temsirolimus	×	×	×	×	● (II)
ipatasertib, atezolizumab	×	×	×	×	● (I/II)
TAS-117, futibatinib	×	×	×	×	● (I/II)
everolimus + chemotherapy	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
paxalisib	×	×	×	×	○ (II)
alpelisib, chemotherapy	×	×	×	×	○ (I/II)
atezolizumab, ipatasertib	×	×	×	×	○ (I/II)
copanlisib, chemotherapy	×	×	×	×	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	×	×	×	×	○ (I/II)

### PIK3CA amplification

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
ipatasertib	×	×	×	×	● (II)
temsirolimus	×	×	×	×	● (II)
ipatasertib, atezolizumab	×	×	×	×	● (I/II)
TAS-117, futibatinib	×	×	×	×	● (I/II)
palbociclib, gedatolisib	×	×	×	×	● (I)
everolimus + chemotherapy	×	×	×	×	○ (II)
inavolisib, chemotherapy	×	×	×	×	○ (II)
TQ-B3525	×	×	×	×	○ (II)
alpelisib, chemotherapy	×	×	×	×	○ (I/II)
atezolizumab, ipatasertib	×	×	×	×	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	×	×	×	×	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ● In this cancer type and other cancer types    
 ✕ No evidence

### PIK3CA aberration

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
ipatasertib	✕	✕	✕	✕	● (II)
temsirolimus	✕	✕	✕	✕	● (II)
ipatasertib, atezolizumab	✕	✕	✕	✕	● (I/II)
TAS-117, futibatinib	✕	✕	✕	✕	● (I/II)
everolimus + chemotherapy	✕	✕	✕	✕	○ (II)
inavolisib, chemotherapy	✕	✕	✕	✕	○ (II)
alpelisib, chemotherapy	✕	✕	✕	✕	○ (I/II)
atezolizumab, ipatasertib	✕	✕	✕	✕	○ (I/II)
hormone therapy, afuresertib, steroid, chemotherapy	✕	✕	✕	✕	○ (I/II)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<b>PIK3CA E542K mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<b>PIK3CA E545K mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<b>PIK3CA H1047L mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<b>PIK3CA H1047R mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	37
<b>PIK3CA H1047Y mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	36
<b>PIK3CA E545A mutation</b> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1, 2</sup>	33

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO



## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA E545D [c.1635G&gt;T]</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1,2</sup>	33
<i>PIK3CA E545G mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1,2</sup>	33
<i>PIK3CA Q546E mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1,2</sup>	31
<i>PIK3CA Q546R mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1,2</sup>	31
<i>PIK3CA C420R mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy <sup>1,2</sup>	31
<i>PIK3CA H1047 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	36
<i>PIK3CA activating mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	34
<i>PIK3CA E545 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	33
<i>PIK3CA E542 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	32
<i>PIK3CA exon 20 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	31
<i>PIK3CA exon 9 mutation</i> Prognostic significance: None Diagnostic significance: None	None	alpelisib + hormone therapy	31
<i>PIK3CA mutation</i> Prognostic significance: None Diagnostic significance: None	None	None	31
<i>PIK3CA mutation status</i> Prognostic significance: None Diagnostic significance: None	None	None	14

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Relevant Biomarkers (continued)

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA</i> amplification Prognostic significance: None Diagnostic significance: None	None	None	12
<i>PIK3CA</i> aberration Prognostic significance: None Diagnostic significance: None	None	None	10

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

## Clinical Trials Summary

### PIK3CA E542K mutation

NCT ID	Title	Phase
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral a-specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II

## Clinical Trials Summary (continued)

### PIK3CA E542K mutation (continued)

NCT ID	Title	Phase
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
No NCT ID	BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping --- FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II

## Clinical Trials Summary (continued)

### PIK3CA E542K mutation (continued)

NCT ID	Title	Phase
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA E545K mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I

## Clinical Trials Summary (continued)

### PIK3CA E545K mutation (continued)

NCT ID	Title	Phase
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
No NCT ID	BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II

## Clinical Trials Summary (continued)

### PIK3CA E545K mutation (continued)

NCT ID	Title	Phase
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping --- FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA H1047L mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II



## Clinical Trials Summary (continued)

### PIK3CA H1047L mutation (continued)

NCT ID	Title	Phase
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
No NCT ID	BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II

## Clinical Trials Summary (continued)

### PIK3CA H1047L mutation (continued)

NCT ID	Title	Phase
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA H1047R mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I



## Clinical Trials Summary (continued)

### PIK3CA H1047R mutation (continued)

NCT ID	Title	Phase
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
No NCT ID	BCT 1901 (CAPTURE): A Phase II Randomised Study To Evaluate Alpelisib Plus Fulvestrant Versus Capecitabine In Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients With PIK3CA Mutant Circulating DNA.	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III

## Clinical Trials Summary (continued)

### PIK3CA H1047R mutation (continued)

NCT ID	Title	Phase
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

## Clinical Trials Summary (continued)

### PIK3CA H1047Y mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III

## Clinical Trials Summary (continued)

### PIK3CA H1047Y mutation (continued)

NCT ID	Title	Phase
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

## Clinical Trials Summary (continued)

### PIK3CA E545A mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II

## Clinical Trials Summary (continued)

### PIK3CA E545A mutation (continued)

NCT ID	Title	Phase
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA E545D [c.1635G>T]

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II



## Clinical Trials Summary (continued)

### PIK3CA E545D [c.1635G>T] (continued)

NCT ID	Title	Phase
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II

## Clinical Trials Summary (continued)

### PIK3CA E545D [c.1635G>T] (continued)

NCT ID	Title	Phase
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA E545G mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II



## Clinical Trials Summary (continued)

### PIK3CA E545G mutation (continued)

NCT ID	Title	Phase
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II

## Clinical Trials Summary (continued)

### PIK3CA E545G mutation (continued)

NCT ID	Title	Phase
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA Q546E mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II

## Clinical Trials Summary (continued)

### PIK3CA Q546E mutation (continued)

NCT ID	Title	Phase
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II

## Clinical Trials Summary (continued)

### PIK3CA Q546E mutation (continued)

NCT ID	Title	Phase
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA Q546R mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I

## Clinical Trials Summary (continued)

### PIK3CA Q546R mutation (continued)

NCT ID	Title	Phase
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II

## Clinical Trials Summary (continued)

### PIK3CA Q546R mutation (continued)

NCT ID	Title	Phase
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping --- FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA C420R mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I



## Clinical Trials Summary (continued)

### PIK3CA C420R mutation (continued)

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I

## Clinical Trials Summary (continued)

### PIK3CA C420R mutation (continued)

NCT ID	Title	Phase
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA H1047 mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I



## Clinical Trials Summary (continued)

### PIK3CA H1047 mutation (continued)

NCT ID	Title	Phase
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II

## Clinical Trials Summary (continued)

### PIK3CA H1047 mutation (continued)

NCT ID	Title	Phase
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA activating mutation

NCT ID	Title	Phase
NCT04632992	MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I

## Clinical Trials Summary (continued)

### PIK3CA activating mutation (continued)

NCT ID	Title	Phase
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT04216472	A Phase-II, Two-Cohort Trial of Neoadjuvant Nab-Paclitaxel and Alpelisib in Anthracycline Refractory Triple Negative Breast Cancer With PIK3CA or PTEN Alterations	II
NCT05025735	Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II

## Clinical Trials Summary (continued)

### PIK3CA activating mutation (continued)

NCT ID	Title	Phase
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping --- FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA E545 mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT04586335	Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral $\alpha$ -specific PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors.	I
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I

## Clinical Trials Summary (continued)

### PIK3CA E545 mutation (continued)

NCT ID	Title	Phase
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II

## Clinical Trials Summary (continued)

### PIK3CA E545 mutation (continued)

NCT ID	Title	Phase
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA E542 mutation

NCT ID	Title	Phase
NCT04317105	A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in Patients With Advanced Solid Tumors	I/II
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I



## Clinical Trials Summary (continued)

### PIK3CA E542 mutation (continued)

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I

## Clinical Trials Summary (continued)

### PIK3CA E542 mutation (continued)

NCT ID	Title	Phase
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA exon 20 mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II



## Clinical Trials Summary (continued)

### PIK3CA exon 20 mutation (continued)

NCT ID	Title	Phase
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II

## Clinical Trials Summary (continued)

### PIK3CA exon 20 mutation (continued)

NCT ID	Title	Phase
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA exon 9 mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III

## Clinical Trials Summary (continued)

### PIK3CA exon 9 mutation (continued)

NCT ID	Title	Phase
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus OLaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

## Clinical Trials Summary (continued)

### PIK3CA mutation

NCT ID	Title	Phase
NCT03239015	Efficacy and Safety of Targeted Precision Therapy in Refractory Tumor With Druggable Molecular Event	II
NCT04589845	Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial	II
NCT03842228	A Phase Ib Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients With Advanced Solid Tumors	I
NCT03006172	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Inavolisib as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Breast Cancer	I
No NCT ID	A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel and with or without targeted therapies in patients with locally advanced or metastatic solid tumors	I
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT04192981	A Phase I Study With Expansion Cohort of Concurrent GDC-0084 With Radiation Therapy for Patients With Solid Tumor Brain Metastases or Leptomeningeal Metastases Harboring PI3K Pathway Mutations	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04251533	A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	III
NCT04191499	A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GDC-0077 Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Patients With PIK3CA-Mutant, Hormone Receptor-Positive, Her2-Negative, Locally Advanced or Metastatic Breast Cancer	II/III
NCT04524000	A Phase II Open-label, 2-Part, Multi-center Study of BYL719 (Alpelisib) in Combination With Fulvestrant for Men and Postmenopausal Women With PIK3CA Mutation Hormone Receptor (HR) Positive, HER2-negative, Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment in Japan	II
NCT04544189	A Phase II Randomized Double-blind, Placebo-controlled Study of Alpelisib in Combination With Fulvestrant for Chinese Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, PIK3CA Mutant Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor (AI) Treatment, Including a Subset With Pharmacokinetic Analysis	II

## Clinical Trials Summary (continued)

### PIK3CA mutation (continued)

NCT ID	Title	Phase
NCT04762979	A Phase II, Single Arm, Non-randomized Study of Alpelisib (BYL719) in Combination With Continued Endocrine Therapy Following Progression on Endocrine Therapy in Hormone Receptor Positive, HER2 Negative, PIK3CA Mutant Metastatic Breast Cancer	II
NCT04053322	An International Multicenter Phase II Trial of Durvalumab (MEDI4736) Plus Olaparib Plus Fulvestrant in Metastatic or Locally Advanced ER-positive, HER2-negative Breast Cancer Patients Selected Using Criteria That Predict Sensitivity to Olaparib	II
NCT03834740	A Phase 0/II Study of Ribociclib (LEE011) in Combination With Everolimus in Preoperative Rb-Intact Recurrent High-Grade Glioma Patients Scheduled for Resection to Evaluate Central Nervous System (CNS) Penetration	II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04495621	Open-label, Multicentre, Phase Ib/II Study of Men1611, A PI3K Inhibitor, and Cetuximab in Patients With PIK3CA Mutated Metastatic Colorectal Cancer Failing Irinotecan, Oxaliplatin, 5-FU and Anti-EGFR Containing Regimens	I/II
NCT04188548	EMBER: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination With Anticancer Therapies for Patients With ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	I
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA mutation status

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03155620	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	II

## Clinical Trials Summary (continued)

### PIK3CA mutation status (continued)

NCT ID	Title	Phase
NCT03213678	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase II Subprotocol of LY3023414 in Patients With Solid Tumors	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04345913	A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination With Copanlisib in Patients With Metastatic Triple Negative Breast Cancer	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT03994796	Genomically-Guided Treatment Trial in Brain Metastases	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA amplification

NCT ID	Title	Phase
NCT03065062	Phase I Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the PI3K/mTOR Inhibitor Gedatolisib (PF-05212384) for Patients With Advanced Squamous Cell Lung, Pancreatic, Head & Neck and Other Solid Tumors	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04836663	A Open-label, Multicenter Phase II Study of TQ-B3525 Tablets in Subjects With PIK3CA and/or PIK3R1/2 Gene-altered Recurrent/Metastatic Advanced Gynecologic Tumors	II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II



## Clinical Trials Summary (continued)

### PIK3CA amplification (continued)

NCT ID	Title	Phase
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II

### PIK3CA aberration

NCT ID	Title	Phase
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II
No NCT ID	Phase I/II Study of TAS-117 In Combination With TAS-120 In Patients With Advanced Solid Tumors	I/II
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II
NCT03673787	Ice-CAP: A Phase I Trial of Ipatasertib in Combination With Atezolizumab in Patients With Advanced Solid Tumours With PI3K Pathway Hyperactivation.	I/II
NCT04526470	Phase IB/II Study of Alpelisib in Combination With Paclitaxel in Patients With PIK3CA-altered Metastatic/Recurrent Gastric Cancer	I/II
NCT04395989	An Umbrella Trial Based on Molecular Pathway for Patients With Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer (FUTURE SUPER)	II
NCT04849364	A Phase II Circulating Tumor DNA Enriched, Genomically Directed Post-neoadjuvant Trial for Patients With Residual Triple Negative Breast Cancer (PERSEVERE)	II
NCT04486352	A Phase IB/II Multi-Cohort Study of Targeted Agents With Atezolizumab for Patients With Recurrent or Persistent Endometrial Cancer	I/II
NCT03805399	Precision Treatment of Refractory Triple Negative Breast Cancer Based on Molecular Subtyping — FUSCC-TNBC- Umbrella Trial	I/II
NCT04060394	A Phase I/II Dose-Escalation and Efficacy Study of LAE001/Prednisone Plus Afuresertib in Patients With Metastatic Castration-resistant Prostate Cancer Following Standard of Care Treatment.	I/II