



[Oncofocus] Patient Test Report

ONC17-0005

Surname

Requesting clinician

Forename

DOB

Date requested

Gender

Histology #

Tumour %

Primary site Left Breast

Tumour % 80

Tumour subtype Invasive Ductal Carcinoma

(macrodissected)

Tissue type Left Breast

Comment:

The DNA and RNA extracted from this sample were of optimal quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics.

221 genes were targeted using 2530 unique amplicons covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are linked to 485 anti-cancer targeted therapies.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Breast Cancer

● In this cancer type ○ In other cancer type ● In this cancer type and other cancer types ❌ Contraindicated ⚠️ Both for use and contraindicated ✖ No evidence

Gene Variant	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
PTEN p.(H259fs) c.774_774delC	✖	✖	✖	✖	● (12)
PIK3CA p.(H1047R) c.3140A>G	✖	✖	✖	✖	● (18)
TP53 p.(L194P) c.581T>C	✖	✖	✖	✖	● (7)

EMA: European Medicine Agency, **US-FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **US-NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence. Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value of 97%. Copy number variants; amplifications of a >5% confidence value of ≥4 after normalization and deletions of ≤1 are classified as present when the tumour% >50%. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control. With a sensitivity of 99% and PPV of 99%. Supplementary technical information is available upon request.

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Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

Relevant Therapy Summary

In this cancer type
 In other cancer type
 In this cancer type and other cancer types
 ⊘ Contraindicated
 ⚠ Both for use and contraindicated
 ✕ No evidence

PTEN p.(H259fs) c.774_774delC

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
alpelisib	✕	✕	✕	✕	● (II)
everolimus	✕	✕	✕	✕	● (II)
GSK-2636771	✕	✕	✕	✕	● (II)
olaparib + vistusertib	✕	✕	✕	✕	● (II)
talazoparib	✕	✕	✕	✕	● (II)
selumetinib + vistusertib	✕	✕	✕	✕	● (I/II)
AZD-5363 + fulvestrant	✕	✕	✕	✕	● (I)
AZD-5363 + olaparib	✕	✕	✕	✕	● (I)
AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib	✕	✕	✕	✕	● (I)
MSC-2363318A	✕	✕	✕	✕	● (I)
palbociclib + pictilisib, palbociclib + tasesisib	✕	✕	✕	✕	● (I)
PQR-309	✕	✕	✕	✕	● (I)

PIK3CA p.(H1047R) c.3140A>G

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
alpelisib + fulvestrant, fulvestrant + placebo	✕	✕	✕	✕	● (III)
fulvestrant + placebo, tasesisib + fulvestrant	✕	✕	✕	✕	● (III)
alpelisib	✕	✕	✕	✕	● (II)
alpelisib + letrozole, buparlisib + letrozole, letrozole + placebo	✕	✕	✕	✕	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

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Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

Relevant Therapy Summary (continued)

In this cancer type
 In other cancer type
 In this cancer type and other cancer types
 Contraindicated
 Both for use and contraindicated
 No evidence

PIK3CA p.(H1047R) c.3140A>G (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
AZD-5363 + olaparib	×	×	×	×	● (II)
everolimus	×	×	×	×	● (II)
letrozole + placebo, taselisib + letrozole	×	×	×	×	● (II)
sirolimus	×	×	×	×	● (II)
taselisib	×	×	×	×	● (II)
copanlisib + trastuzumab	×	×	×	×	● (I/II)
selumetinib + vistusertib	×	×	×	×	● (I/II)
taselisib + fulvestrant	×	×	×	×	● (I/II)
alpelisib + everolimus, alpelisib + everolimus + exemestane, alpelisib + exemestane	×	×	×	×	● (I)
ARQ-751	×	×	×	×	● (I)
AZD-5363	×	×	×	×	● (I)
MSC-2363318A	×	×	×	×	● (I)
palbociclib + pictilisib, palbociclib + taselisib	×	×	×	×	● (I)
PQR-309	×	×	×	×	● (I)

TP53 p.(L194P) c.581T>C

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention	×	×	×	×	● (II)
MK-1775 + olaparib	×	×	×	×	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

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Relevant Therapy Summary (continued)

In this cancer type
 In other cancer type
 In this cancer type and other cancer types
 Contraindicated
 Both for use and contraindicated
 No evidence

TP53 p.(L194P) c.581T>C (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
olaparib + chemotherapy + radiation therapy + surgical intervention	×	×	×	×	● (II)
ixazomib + vorinostat	×	×	×	×	● (I)
MK-1775	×	×	×	×	● (I)
pembrolizumab + p53MVA	×	×	×	×	● (I)
SGT-53, SGT-53 + chemotherapy	×	×	×	×	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-09-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

PTEN p.(H259fs) c.774_774delC

NCT02506556

A Phase II Exploratory, Open-label, Single Arm Study of BYL719 Monotherapy, a Selective Phosphatidylinositol 3-kinase (PI3K) Alpha Inhibitor, in Adult Patients With Advanced Breast Cancer Progressing After First Line Therapy.

Cancer type: Breast Cancer

Variant class: PTEN mutation

Other identifiers: ACTRN12615000850572, CT772, LL14/02, PIKNIC, TrialTroveID-261995

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER positive

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Country: Australia

NCT02401347

A Phase II Clinical Trial of BMN 673 in BRCA1 and BRCA2 Wild-Type Patients With (i) Advanced Triple-Negative Breast Cancer and Homologous Recombination Deficiency as Assessed by the HRD Assay, and (ii) Advanced HER2-Negative Breast Cancer With Either a Germline or Somatic Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

Cancer type: Breast Cancer

Variant class: PTEN mutation

Other identifiers: BRS0050, NCI-2015-00036, TBB, TrialTroveID-254540

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 wild type

Phase: II

Therapy: talazoparib

Country: United States

US State: CA

US Contact: Pei Jen Chang [650-725-0866; peijenc@stanford.edu]

PTEN p.(H259fs) c.774_774delC (continued)**NCT02101385**

A Phase II Randomized Controlled Trial of Genomically Directed Therapy After Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer: Hoosier Oncology Group BRE12-158

Cancer type: Breast Cancer

Variant class: PTEN aberration

Other identifiers: BRE12-158, HCRN BRE 12-158, HCRN-BRE12-158, NCI-2015-00307, STU00098383, TrialTroveID-206154

Population segments: First line, HER2 negative, Stage 0, Stage I, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: II

Therapy: everolimus

Country: United States

US States: AL, DC, FL, GA, IL, IN, MA, MD, MO, NE, OK, PA, TN, TX, VA, WI

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02583542

A Phase Ib/Ila Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.

Cancer type: Breast Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725

Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Country: United Kingdom

PTEN p.(H259fs) c.774_774delC (continued)**NCT01226316**

A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients with Advanced Solid Malignancies

Cancer type: Breast Cancer

Variant class: PTEN mutation

Other identifiers: 102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773

Population segments: Adenocarcinoma, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: I

Therapy: AZD-5363 + fulvestrant

Countries: Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States

US States: CA, CO, CT, NY, OK, SC, TN, TX

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

NCT02338622

A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours

Cancer type: Breast Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550

Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: I

Therapy: AZD-5363 + olaparib

Country: United Kingdom

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 MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER, TrialTroveID-200294

Population segments: Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: everolimus

Country: France

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Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

PTEN p.(H259fs) c.774_774delC (continued)**NCT02465060**

Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor**Variant class:** PTEN mutation**Other identifiers:** CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH, TrialTroveID-258747**Population segments:** ALK, EGFR, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV**Other inclusion criteria:** PTEN expression**Phase:** II**Therapy:** GSK-2636771**Country:** 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, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WV, WY**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.**NCT02576444**

A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor**Variant class:** PTEN mutation**Other identifiers:** 1508016363, OLAPCO, TrialTroveID-266161**Population segments:** First line, Second line or greater/Refractory/Relapsed, Stage IV**Phase:** II**Therapy:** olaparib + vistusertib**Country:** United States**US State:** CT**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

PTEN p.(H259fs) c.774_774delC (continued)**NCT01884285**

A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Anti-tumour Activity of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB mutated/ amplified Advanced Solid Malignancies as Monotherapy and in Combination with Abiraterone Acetate or AZD2014

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: 13-300, 20131275, D4620C00001, EudraCT Number: 2013-000703-17, IRAS ID: 129536, NCI-2013-02191, TrialTroveID-189056

Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapies: AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib

Countries: Canada, Spain, United Kingdom, United States

US States: MA, MI, WA, WI

US Contact: AstraZeneca Clinical Study Information [800-236-9933; ClinicalTrialTransparency@astrazeneca.com]

NCT01971515

A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PTEN aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334

Population segments: Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MSC-2363318A

Country: United States

US States: CA, MI, TX, VT

US Contact: US Medical Information [888-275-7376]

NCT02338622

A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550

Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: AZD-5363 + olaparib

Country: United Kingdom

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Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

PTEN p.(H259fs) c.774_774delC (continued)**NCT02389842**

PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With Palbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Country: United Kingdom

NCT02483858

Phase I Study of Oral PQR309 in Patients With Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: EudraCT Number: 2015-003919-38, I 258914, IRAS ID: 193390, PQR309-003, REec-2016-2264, TrialTroveID-260655

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: PQR-309

Country: United States

US State: NY

US Contact: Dr. Alex Adjei [Alex.Adjei@RoswellPark.org]

PIK3CA p.(H1047R) c.3140A>G**NCT02437318**

A Phase III Randomized Double-blind, Placebo Controlled Study of Alpelisib in Combination with Fulvestrant for Men and Postmenopausal Women with Hormone Receptor Positive, HER2-negative Advanced Breast Cancer which Progressed on or after Aromatase Inhibitor Treatment

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: CBYL719C2301, CBYL719C2301 / SOLAR-1, CTRI/2016/06/007016, DRKS00008757, EudraCT Number: 2015-000340-42, NCI-2015-01171, SOLAR-1, TrialTroveID-257091

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER positive and/or PR positive

Phase: III

Therapies: alpelisib + fulvestrant, fulvestrant + placebo

Countries: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Chile, Czech Republic, France, Germany, Greece, Hong Kong, Hungary, Israel, Italy, Japan, Lebanon, Netherlands, Peru, Republic of Korea, Romania, Russian Federation, Spain, Sweden, Taiwan, Thailand, United Arab Emirates, United Kingdom, United States

US States: AR, AZ, CA, FL, GA, IL, IN, KS, KY, LA, MA, MD, MI, MO, MT, NY, OH, OR, PA, SC, SD, TN, TX, UT, VA, WA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02340221

A Phase III, Double-blind, Placebo Controlled, Randomized Study of Taselisib plus Fulvestrant Versus Placebo Plus Fulvestrant in Postmenopausal Women with Estrogen receptor-positive and Her2-negative Locally Advanced or Metastatic Breast Cancer who have Disease Recurrence or Progression During or After Aromatase Inhibitor Therapy

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 15-111, 15-153, 15-ROC-5, BRTPIPER, CT714, CT714, EudraCT Number: 2014-003185-25, GO29058, NCI-2015-01649, REec-2015-1381, SANDPIPER, TrialTroveID-222349

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER positive

Exclusion criteria variant class: ERBB2 amplification

Phase: III

Therapies: fulvestrant + placebo, tasiselisib + fulvestrant

Countries: Australia, Austria, Bosnia and Herzegovina, Bulgaria, Canada, Colombia, Czech Republic, Finland, France, Germany, Greece, Italy, Mexico, Netherlands, Peru, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Spain, Sweden, Taiwan, Turkey, United States

US States: AZ, CA, GA, IL, MD, MN, MO, NJ, NY, OR

US Contact: Reference Study ID Number: GO29058 [888-662-6728; global.roche.genentechtrials@roche.com]

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02506556**

A Phase II Exploratory, Open-label, Single Arm Study of BYL719 Monotherapy, a Selective Phosphatidylinositol 3-kinase (PI3K) Alpha Inhibitor, in Adult Patients With Advanced Breast Cancer Progressing After First Line Therapy.

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: ACTRN12615000850572, CT772, LL14/02, PIKNIC, TrialTroveID-261995

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER positive

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Country: Australia

NCT01923168

A Phase II Randomized, Double-blind Placebo Controlled, Study of Letrozole with or without BYL719 or Buparlisib, for the Neoadjuvant Treatment of Postmenopausal Women with Hormone Receptor-positive HER2-negative Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 00054363, 041311, 14-202, 14752, 20132066, ABCSG-40, BRTA2201, CBYL719A2201, CTMS# 15-2039, EudraCT Number: 2013-001862-41, J13178, NCI-2014-00149, NEO-ORB, NL46099.058.13, P50 CA098131, REec-2013-0617, TBCRC025, TrialTroveID-192163, USO 13076, USONCOLOGY 13076, VICCBRE1393

Population segments: HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III

Other inclusion criteria: ERBB2 wild type, ER positive and/or PR positive

Phase: II

Therapies: alpelisib + letrozole, buparlisib + letrozole, letrozole + placebo

Countries: Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Colombia, Czech Republic, Germany, Hong Kong, Israel, Italy, Japan, Lebanon, Netherlands, Spain, United States

US States: CA, GA, MA, MD, MN, NC, OR, TX, VA, WA

US Contact: Novartis Pharmaceuticals [888-669-6682]

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02273973**

A Phase II Randomized, Double-Blind, Study of Neoadjuvant Letrozole Plus GDC-0032 Versus Letrozole Plus Placebo in Post-Menopausal Women With ER-positive/HER2-negative, Early Stage Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 15-020, 2014-0580, ABCSG 38, BIG-3-13, EORTC 1319, EORTC-1319-BCG, EORTC-1319-BCG - Lorelei, EudraCT Number: 2013-000568-28, GO28888, IBCSG 46-13 LORELEI, IRAS ID: 137300, LORELEI, NCI-2014-02653, SOLTI 1205, TrialTroveID-210342, UKCRN ID: 16325

Population segments: HER2 negative, Neoadjuvant, Stage I, Stage II, Stage III

Other inclusion criteria: ERBB2 wild type, ER positive

Phase: II

Therapies: letrozole + placebo, taselisib + letrozole

Countries: Australia, Austria, Belgium, Chile, Czech Republic, El Salvador, France, Germany, Guatemala, Hungary, Italy, Panama, Poland, Portugal, Republic of Korea, Spain, Switzerland, United Kingdom, United States

US States: CA, MA, NY, TX

US Contact: Reference Study ID Number: GO28888 [888-662-6728; global.roche.genentechtrials@roche.com]

NCT02101385

A Phase II Randomized Controlled Trial of Genomically Directed Therapy After Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer: Hoosier Oncology Group BRE12-158

Cancer type: Breast Cancer

Variant class: PIK3CA aberration

Other identifiers: BRE12-158, HCRN BRE 12-158, HCRN-BRE12-158, NCI-2015-00307, STU00098383, TrialTroveID-206154

Population segments: First line, HER2 negative, Stage 0, Stage I, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: II

Therapy: everolimus

Country: United States

US States: AL, DC, FL, GA, IL, IN, MA, MD, MO, NE, OK, PA, TN, TX, VA, WI

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02646319**

A Pilot Study of a Rapid Access Platform for Investigational Drugs (RAPID) in Advanced Cancers

Cancer type: Breast Cancer

Variant class: PIK3CA aberration

Other identifiers: MC1313, NCI-2015-02151, RAPID, TrialTroveID-270911

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: sirolimus

Country: United States

US States: AZ, MN

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02705859

Phase Ib/II Clinical Trial of Copanlisib in Combination With Trastuzumab in Pretreated Recurrent or Metastatic HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: EudraCT Number: 2015-003687-36, ICORG 15-02, ICORG1502, Panther, TrialTroveID-272101

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I/II

Therapy: copanlisib + trastuzumab

Country: Ireland

NCT01296555

An Open-Label, Phase I/II, Dose Escalation Study Evaluating the Safety and Tolerability of GDC-0032 in Patients With Locally Advanced or Metastatic Solid Tumors and in Combination With Endocrine Therapy in Patients With Locally Advanced or Metastatic Hormone Receptor-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 11-010, 13-149, 2013-0375, 201405133, EudraCT Number: 2012-002042-21, GO00886, JapicCTI-142630, JO29196, NCI-2011-00912, PMT4979g, TrialTroveID-142345, VICCPHI1248

Population segments: HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER positive

Phase: I/II

Therapy: taselisib + fulvestrant

Countries: Canada, Spain, United States

US States: AZ, CA, CT, FL, IL, MA, NY, OK, TN, TX, WA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT01296555**

An Open-Label, Phase I/II, Dose Escalation Study Evaluating the Safety and Tolerability of GDC-0032 in Patients With Locally Advanced or Metastatic Solid Tumors and in Combination With Endocrine Therapy in Patients With Locally Advanced or Metastatic Hormone Receptor-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 11-010, 13-149, 2013-0375, 201405133, EudraCT Number: 2012-002042-21, G000886, JapicCTI-142630, JO29196, NCI-2011-00912, PMT4979g, TrialTroveID-142345, VICCPHI1248

Population segments: HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: I/II

Therapy: taselisib + fulvestrant

Countries: Canada, Spain, United States

US States: AZ, CA, CT, FL, IL, MA, NY, OK, TN, TX, WA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02583542

A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.

Cancer type: Breast Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725

Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Country: United Kingdom

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02077933**

A Phase Ib Dose-finding Study of BYL719 Plus Everolimus and BYL719 Plus Everolimus Plus Exemestane in Patients With Advanced Solid Tumors, With Dose-expansion Cohorts in Renal Cell Cancer (RCC), Pancreatic Neuroendocrine Tumors (pNETs), and Advanced Breast Cancer (BC) Patients.

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 14-097, CBYL719Z2102, CSET 2136, EudraCT Number: 2013-004829-86, IRAS ID: 152947, NL48012.031.14, NOV-CBYL719Z2102, REec-2016-2336, TrialTroveID-204036

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 wild type, ER positive, PR positive

Phase: I

Therapies: alpelisib + everolimus, alpelisib + everolimus + exemestane, alpelisib + exemestane

Countries: France, Germany, Hong Kong, Hungary, Italy, Netherlands, Spain, United Kingdom, United States

US States: AR, CA, NY

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT01226316

A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients with Advanced Solid Malignancies

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773

Population segments: Adenocarcinoma, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: I

Therapy: AZD-5363

Countries: Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States

US States: CA, CO, CT, NY, OK, SC, TN, TX

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

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02389842**

PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With Palbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER negative

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Country: United Kingdom

NCT02389842

PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With Palbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER positive

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Country: United Kingdom

NCT02389842

PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With Palbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Country: United Kingdom

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02338622**

A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours

Cancer type: Breast Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550

Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: I

Therapy: AZD-5363 + olaparib

Country: United Kingdom

NCT02576444

A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

Population segments: First line, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: AZD-5363 + olaparib

Country: United States

US State: CT

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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 MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER, TrialTroveID-200294

Population segments: Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: everolimus

Country: France

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02449538**

Study to Evaluate the Safety and Efficacy of Everolimus, in Subjects With PIK3CA Amplification, PTEN Loss and PIK3CA Mutation Refractory Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 2015-01-117, TrialTroveID-257722

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Exclusion criteria variant classes: BRAF V600 mutation, KRAS G12 mutation, KRAS G13 mutation

Phase: II

Therapy: everolimus

Country: Republic of Korea

NCT02449564

The Pilot Study Evaluate the Safety and Efficacy of Sirolimus in Patients With PIK3CA Mutation and/or PIK3CA Amplification Refractory Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 2014-10-030, TrialTroveID-257741

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: II

Therapy: sirolimus

Country: Republic of Korea

NCT02465060

Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH, TrialTroveID-258747

Population segments: ALK, EGFR, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Exclusion criteria variant classes: PTEN deletion, RAS mutation

Phase: II

Therapy: taselisib

Country: 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, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WV, WY

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT02761694**

A Phase I Dose Escalation Study of ARQ 751 in Adult Subjects With Advanced Solid Tumors With AKT1, 2, 3 Genetic Alterations, Activating PI3K Mutations or PTEN-null

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA activating mutation

Other identifiers: ARQ 751-101, PTEN-null, TrialTroveID-272167

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: ARQ-751

Country: United States

US State: NV

US Contact: ArQule, Inc. [781-994-0300; ClinicalTrials@arqule.com]

NCT01226316

A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients with Advanced Solid Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773

Population segments: Adenocarcinoma, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: AZD-5363

Countries: Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States

US States: CA, CO, CT, NY, OK, SC, TN, TX

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

NCT02389842

PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With Palbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + tasiselisib

Country: United Kingdom

PIK3CA p.(H1047R) c.3140A>G (continued)**NCT01971515**

A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334

Population segments: Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MSC-2363318A

Country: United States

US States: CA, MI, TX, VT

US Contact: US Medical Information [888-275-7376]

NCT02338622

A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550

Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: AZD-5363 + olaparib

Country: United Kingdom

NCT02483858

Phase I Study of Oral PQR309 in Patients With Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: EudraCT Number: 2015-003919-38, I 258914, IRAS ID: 193390, PQR309-003, REec-2016-2264, TrialTroveID-260655

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: PQR-309

Country: United States

US State: NY

US Contact: Dr. Alex Adjei [Alex.Adjei@RoswellPark.org]

TP53 p.(L194P) c.581T>C**NCT02624973**Personalized Treatment of High-risk
Mammary Cancer - the PETREMAC Trial**Cancer type:** Breast Cancer**Variant class:** TP53 mutation**Other identifiers:** 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482**Population segments:** Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative**Other inclusion criteria:** ER negative, PR negative**Phase:** II**Therapies:** hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention**Country:** Norway**NCT02624973**Personalized Treatment of High-risk
Mammary Cancer - the PETREMAC Trial**Cancer type:** Breast Cancer**Variant class:** TP53 mutation**Other identifiers:** 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482**Population segments:** Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative**Other inclusion criteria:** ER positive, PR positive**Phase:** II**Therapies:** hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention**Country:** Norway**NCT02624973**Personalized Treatment of High-risk
Mammary Cancer - the PETREMAC Trial**Cancer type:** Breast Cancer**Variant class:** TP53 mutation**Other identifiers:** 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482**Population segments:** Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative**Other inclusion criteria:** ERBB2 wild type, ER negative, PR negative**Phase:** II**Therapy:** olaparib + chemotherapy + radiation therapy + surgical intervention**Country:** Norway

TP53 p.(L194P) c.581T>C (continued)**NCT02432963**

A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab

Cancer type: Breast Cancer**Variant class:** TP53 mutation**Other identifiers:** 116634, 122284, 122771, 124524, 15002, NCI-2015-00653, TrialTroveID-256830**Population segments:** HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative, Unresectable**Other inclusion criteria:** ERBB2 wild type, ER negative, PR negative**Phase:** I**Therapy:** pembrolizumab + p53MVA**Country:** United States**US State:** CA**US Contact:** Vincent Chung [800-826-4673]**NCT02576444**

A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor**Variant class:** TP53 mutation**Other identifiers:** 1508016363, OLAPCO, TrialTroveID-266161**Population segments:** First line, Second line or greater/Refractory/Relapsed, Stage IV**Phase:** II**Therapy:** MK-1775 + olaparib**Country:** United States**US State:** CT**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.**NCT02042989**

A Phase I Study of MLN9708 and Vorinostat to Target Autophagy in Patients With Advanced p53 Mutant Malignancies

Cancer type: Unspecified Solid Tumor**Variant class:** TP53 mutation**Other identifiers:** 2013-0511, NCI-2014-01091, TrialTroveID-201319**Population segments:** Line of therapy N/A, Stage III, Stage IV**Phase:** I**Therapy:** ixazomib + vorinostat**Country:** United States**US State:** TX**US Contact:** Dr. Siqing Fu [713-563-1930]

TP53 p.(L194P) c.581T>C (continued)**NCT02610075**

A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: D6015C00003, REFMAL 398, TrialTroveID- 268385

Population segments: Liver mets, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MK-1775

Country: United States

US States: CO, TN

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

NCT02354547

A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1405-1316, SGT53-01-2, TrialTroveID-251586

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Country: United States

US State: TX

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Appendix: Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

PTEN p.(H259fs) c.774_774delC

Variant Class	Evidence Items
PI3K/AKT/MTOR pathway	9
↳ PTEN aberration	2
↳ PTEN mutation	7

PIK3CA p.(H1047R) c.3140A>G

Variant Class	Evidence Items
PI3K/AKT/MTOR pathway	9
↳ PIK3CA aberration	3
↳ PIK3CA mutation	20
↳ PIK3CA activating mutation	1

TP53 p.(L194P) c.581T>C

Variant Class	Evidence Items
TP53 mutation	8

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency Transcript	Variant Effect
PIK3CA	p.(H1047R)	c.3140A>G	COSM775	chr3:178952085	15.48% NM_006218.2	missense
PTEN	p.(H259fs)	c.774_774delC	.	chr10:89717748	38.13% NM_000314.4	frameshift Deletion
TP53	p.(L194P)	c.581T>C	COSM43827	chr17:7578268	36.38% NM_000546.5	missense

ONC17-: 0005

www.oncologica.com

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

Terms and Conditions

The following paragraph on Liability is an extract from the Oncologica Tests' Terms and Conditions. The extract is to draw your attention to particular terms applicable to you but nothing set out here is intended to supersede or override our Terms and Conditions, which can be found on our website at www.oncologica.com under the title Oncologica Tests' Terms and Conditions. Please read these Oncologica Test Terms and Conditions carefully before you submit an order for the Oncologica Tests, as you will be bound by these Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.

6. Liability

6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

6.3 Information compiled in the Oncologica Test Report includes is from publicly available as well as proprietary sources. By updating the source database, Oncologica makes every effort to provide the most accurate and up-to-date information. However, Oncologica does not warrant or represent that the information in the Oncologica Test Report is accurate, timely or complete.

6.4 The Oncologica Test Report contains drug and clinical trial information. However, Oncologica does not warrant or represent that any drug or clinical trial identified by the Oncologica Test will guarantee a therapeutic response for a particular Patient. The drugs listed in an Oncologica Test Report are ranked on clinical evidence as to the predicted efficacy or appropriateness for the Patient. The Patient shall ensure that its physician shall evaluate and interpret the Oncologica Test Report, along with all other available clinical information about the Patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, nor solely on the information contained in the Oncologica Test Report.

6.5 Subject to paragraph 6.10, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Tests, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient's physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient's physician's professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician's use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient's physician.

6.6 Oncologica does not warrant or represent or guarantee that the Oncologica Tests will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Tests are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patient's cancer. In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.

6.7 The Oncologica Test identifies genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:

- (a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;
- (b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;
- (c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

6.9 Subject to the provisions of this Clause 6, Oncologica's total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Test that is the subject of the claim.

6.10 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.11 If the Patient is a consumer (and not a business), the Patient expressly acknowledges and agrees that the Test is supplied to the Patient's specification and therefore there is no right to cancel the Test following acceptance under Clause 2.2. If the Patient is a consumer, then notwithstanding any other provisions of the Contract, none of the Patient's consumer statutory rights are affected.

