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Leading a new era of precision oncology

Oncofocus®

Precision Oncology

ONCOFOCUS® TEST REPORT

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ONC19	-		
Surname	-	**Requester**	-
Forename	-	**Contact details**	-
DOB	-	**Date requested**	-
Gender	-		
Histology #	-	**Tumour %**	-
Primary site	Breast	**Tumour %**	-
Tumour subtype	-	**(macrodissected)**	
Tissue Type	-		

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.

Oncofocus currently targets 505 genes covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are currently linked to 687 anti-cancer targeted therapies/therapy combinations.

The following actionable variants were detected:

Within the 'Current Clinical Trials Information' section of this report, starting on page 8, the NCT numbers are hyperlinks to the clinicaltrials.gov webpages which should be accessed to gain further trial specific information

Sample Cancer Type: Breast Cancer

Clinically Significant Biomarkers

Indicated Contraindicated

Genomic Alteration	Alt allele freq	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
ERBB2 p.(G727A) c.2180G>C	39%	Clinical trials and/or off-label	ado-trastuzumab emtansine	19
BRAF p.(V600E) c.1799T>A	5%	Clinical trials and/or off-label	dabrafenib vemurafenib	13
PIK3CA p.(G1049R) c.3145G>C	58%	Clinical trials and/or off-label	Clinical trials and/or off-label	15

Sources included in relevant therapies: EMA1, FDA2, ESMO, NCCN

Hotspot variants with >10% alternate allele reads are classified as 'detected' with an assay sensitivity and positive predictive value(PPV) of 99%. Copy number variants; amplifications of CN> 6 with the 5% confidence value of ≥4 after normalization and deletions with 95% CI ≤1 are classified as present when the tumour% >50% with a sensitivity of 80% and PPV 100%. Gene Fusions are reported when occurring in >40 counts and meeting the thresholds of assay specific internal RNA quality control with a sensitivity of 92% and PPV of 99%. Supplementary technical information is available upon request.

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.

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Tier Criteria Met

Genomic Alteration	Tier Classification for Breast Cancer
ERBB2 mutation Tier: IIC	IIC: Biomarker is included in ESMO or NCCN guidelines that predict response or resistance to therapies in other cancer types IIC: Biomarker is an inclusion criteria for clinical trials
BRAF mutation Tier: IIC	IIC: Biomarker is included in ESMO or NCCN guidelines that predict response or resistance to therapies in other cancer types IIC: Biomarker is an inclusion criteria for clinical trials
PIK3CA mutation Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials

Reference: Li et al. *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists.* J Mol Diagn. 2017 Jan;19(1):4-23.

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

ERBB2 mutation

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
ado-trastuzumab emtansine	✖	✖	✖	○	✖
afatinib	✖	✖	✖	✖	● (II)
alpelisib	✖	✖	✖	✖	● (II)
atezolizumab + cobimetinib + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
neratinib	✖	✖	✖	✖	● (II)
neratinib + fulvestrant	✖	✖	✖	✖	● (II)
neratinib + fulvestrant, neratinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
neratinib + trastuzumab	✖	✖	✖	✖	● (II)
neratinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
neratinib, neratinib + trastuzumab	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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

ERBB2 mutation (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
poziotinib	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
TAS0728	✖	✖	✖	✖	● (I/II)
darolutamide	✖	✖	✖	✖	● (I)
everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib	✖	✖	✖	✖	● (I)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)
pirotinib	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)
varlitinib + chemotherapy	✖	✖	✖	✖	● (I)

BRAF mutation

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
dabrafenib	✖	✖	✖	○	✖
vemurafenib	✖	✖	✖	○	✖
cobimetinib + vemurafenib, dabrafenib	✖	✖	✖	✖	● (II)
regorafenib	✖	✖	✖	✖	● (II)
sorafenib	✖	✖	✖	✖	● (II)
ASTX029	✖	✖	✖	✖	● (I/II)
cobimetinib	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
abemaciclib + LY3214996 , LY3214996 , LY3214996 + chemotherapy, LY3214996 + midazolam	✖	✖	✖	✖	● (I)
camrelizumab + SHR7390	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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

BRAF mutation (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
cobimetinib + HM-95573	✖	✖	✖	✖	● (I)
HM-95573	✖	✖	✖	✖	● (I)
KO-947	✖	✖	✖	✖	● (I)
LTT-462	✖	✖	✖	✖	● (I)
LXH254 , LXH254 + spartalizumab	✖	✖	✖	✖	● (I)

PIK3CA mutation

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
alpelisib	✖	✖	✖	✖	● (II)
alpelisib + fulvestrant, alpelisib + letrozole	✖	✖	✖	✖	● (II)
capivasertib + olaparib	✖	✖	✖	✖	● (II)
copanlisib	✖	✖	✖	✖	● (II)
everolimus	✖	✖	✖	✖	● (II)
palbociclib + anastrozole, palbociclib + hormone therapy	✖	✖	✖	✖	● (II)
sirolimus	✖	✖	✖	✖	● (II)
temsirolimus	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
capivasertib	✖	✖	✖	✖	● (I)
GDC-0077	✖	✖	✖	✖	● (I)
GDC-0077 + fulvestrant, GDC-0077 + letrozole, GDC-0077 + palbociclib + letrozole	✖	✖	✖	✖	● (I)
gedatolisib + palbociclib	✖	✖	✖	✖	● (I)
LY-3023414 + prexasertib	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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 mutation (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
palbociclib + pictilisib + fulvestrant, palbociclib + taselisib + fulvestrant	✖	✖	✖	✖	● (I)
palbociclib + pictilisib, palbociclib + taselisib	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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.

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Relevant Therapy Details

Current NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated 👎 Not recommended 🛡 Resistance

NCCN information is current as of 2018-08-16. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

ERBB2 mutation

○ ado-trastuzumab emtansine

Cancer type: Non-Small Cell Lung Cancer **Variant class:** ERBB2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Emerging targeted agents

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 6.2018]

BRAF mutation

○ dabrafenib

Cancer type: Thyroid Cancer **Variant class:** BRAF mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Locally Recurrent, Advanced, and/or Metastatic Papillary Carcinoma, Follicular Carcinoma, Hurthle Cell Carcinoma; Not amenable to RAI therapy; Iodine-refractory; Progressive and/or symptomatic disease if clinical trials or other systemic therapies are not available or appropriate (Not specified)

Reference: NCCN Guidelines® - NCCN-Thyroid Carcinoma [Version 1.2018]

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.

BRAF mutation (continued)

vemurafenib

Cancer type: Thyroid Cancer **Variant class:** BRAF mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Locally Recurrent, Advanced, and/or Metastatic Papillary Carcinoma, Follicular Carcinoma, Hurthle Cell Carcinoma; Not amenable to RAI therapy; Iodine-refractory; Progressive and/or symptomatic disease if clinical trials or other systemic therapies are not available or appropriate (Not specified)

Reference: NCCN Guidelines® - NCCN-Thyroid Carcinoma [Version 1.2018]

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.

Current Clinical Trials Information

Clinical Trials information is current as of 2018-09-04. 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'.

ERBB2 mutation

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: ERBB2 mutation

Other identifiers: ACTRN12615000850572, CBYL719XAU01T, CT772, LL14/02, PIKNIC, PIKNIC study

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER positive

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Location: Australia

No NCT ID - see other identifier(s)
An open label, single arm, single agent, phase II trial of neratinib, an irreversible ERBB2 inhibitor, in metastatic ERBB2 mutant, HER2 negative breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: EORTC-1304-BCG - Anabela, EudraCT Number: 2013-004713-40, PUMA-NER-1202

Population segments: HER2 negative, Line of therapy N/A, Stage IV

Phase: II

Therapy: neratinib

Location: Belgium

NCT03182634
A Multiple Parallel Cohort, Multi-centre Phase IIa Trial Aiming to Provide Proof of Principle Efficacy for Designated Targeted Therapies in Patients With Advanced Breast Cancer Where the Targetable Mutation is Identified Through ctDNA plasma-based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) trial

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 31608, EudraCT Number: 2015-003735-36, ICR-CTSU/2015/10056, IRAS 187103, ISRCTN16945804, plasmaMATCH

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

Other inclusion criteria: ER negative

Phase: II

Therapy: neratinib

Location: United Kingdom

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.

ERBB2 mutation (continued)

NCT03182634
A Multiple Parallel Cohort, Multi-centre Phase IIa Trial Aiming to Provide Proof of Principle Efficacy for Designated Targeted Therapies in Patients With Advanced Breast Cancer Where the Targetable Mutation is Identified Through ctDNA plasma-based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) trial

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 31608, EudraCT Number: 2015-003735-36, ICR-CTSU/2015/10056, IRAS 187103, ISRCTN16945804, plasmaMATCH

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

Other inclusion criteria: ER positive

Phase: II

Therapy: neratinib + fulvestrant

Location: United Kingdom

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

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

Phase: II

Therapies: neratinib + fulvestrant, neratinib + trastuzumab + fulvestrant

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

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.

ERBB2 mutation (continued)

NCT01953926
An Open-Label, Phase II Study Of Neratinib In Patients With Solid Tumors With Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) Mutations Or EGFR Gene Amplification

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 13-140, 13-615, 2013-0904, CTA733, EudraCT Number: 2013-002872-42, IRAS ID: 171670, NCI-2014-00495, PUMA-NER-5201, REec-2014-0843, SUMMIT, SUMMIT basket

Population segments: EGFR, Estrogen receptor positive, First line, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: Hormone receptor negative

Phase: II

Therapy: neratinib + trastuzumab

Locations: Australia, Belgium, Denmark, France, Israel, Italy, Republic of Korea, Spain, United States

US States: CA, FL, IL, LA, MA, MO, NY, PA, TN, TX, WI

US Contact: Puma Biotechnology Clinical Operations Senior Director [424-248-6500; ClinicalTrials@pumabiotechnology.com]

NCT01953926
An Open-Label, Phase II Study Of Neratinib In Patients With Solid Tumors With Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) Mutations Or EGFR Gene Amplification

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 13-140, 13-615, 2013-0904, CTA733, EudraCT Number: 2013-002872-42, IRAS ID: 171670, NCI-2014-00495, PUMA-NER-5201, REec-2014-0843, SUMMIT, SUMMIT basket

Population segments: EGFR, Estrogen receptor positive, First line, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: Hormone receptor positive

Phase: II

Therapy: neratinib + trastuzumab + fulvestrant

Locations: Australia, Belgium, Denmark, France, Israel, Italy, Republic of Korea, Spain, United States

US States: CA, FL, IL, LA, MA, MO, NY, PA, TN, TX, WI

US Contact: Puma Biotechnology Clinical Operations Senior Director [424-248-6500; ClinicalTrials@pumabiotechnology.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.

ERBB2 mutation (continued)

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

Other inclusion criteria: ERBB2 negative

Phase: II

Therapies: neratinib, neratinib + trastuzumab

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

Other inclusion criteria: ERBB2 negative, ER negative

Phase: II

Therapies: neratinib, neratinib + trastuzumab

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

NCT02544997
A Phase II, Single-Arm Trial of Poziotinib as Salvage Treatment in Patients With Metastatic Breast Cancer Who Has HER2 or EGFR Mutation or Activated AR or EGFR Pathway

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifier: 2014-11-078

Population segments: HER2 positive, Second line, Stage IV

Exclusion criteria variant class: ERBB2 overexpression

Phase: II

Therapy: poziotinib

Location: Republic of Korea

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.

ERBB2 mutation (continued)

NCT03202316
A Phase II Study of Triple Combination of Atezolizumab + Cobimetinib + Eribulin (ACE) in Patients With Recurrent/ Metastatic Inflammatory Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 status

Other identifiers: 2016-0890, NCI-2017-01601

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

Other inclusion criteria: Hormone receptor status

Phase: II

Therapy: atezolizumab + cobimetinib + chemotherapy

Location: United States

US State: TX

US Contact: Dr. Bora Lim [713-792-2817; blim@mdanderson.org]

NCT03410927
A Phase I/II, Open Label, Multicenter Study to Investigate the Safety, Pharmacokinetics, and Efficacy of TAS0728, an Oral Covalent Binding Inhibitor of HER2, in Subjects With Advanced Solid Tumors With HER2 or HER3 Abnormalities

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 18116, 2017-0994, EudraCT Number: 2017-004415-39, NCI-2018-00211, REFMAL 555, TO-TAS0728-101

Population segments: Adenocarcinoma, Fourth line or greater, HER2 positive, Large Cell, Second line, Stage III, Stage IV, Third line

Phase: I/II

Therapy: TAS0728

Locations: United Kingdom, United States

US States: NY, TN, TX

US Contact: Dr. Mark Kirshbaum [609-750-5300; MKirschbaum@taihooncology.com]

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers

Cancer type: Breast Cancer

Variant class: ERBB2 aberration

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

Population segments: Adenocarcinoma, EGFR, FGFR, HER2 negative, KRAS, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

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.

ERBB2 mutation (continued)

NCT02152943
Combination Treatment With Everolimus, Letrozole and Trastuzumab in Hormone Receptor and HER2/Neu-positive Patients With Advanced Metastatic Breast Cancer and Other Solid Tumors: Evaluating Synergy and Overcoming Resistance

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 2014-0119, NCI-2014-01615

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 positive, Maintenance/Consolidation, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive, PR positive

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Location: United States

US State: TX

US Contact: Dr. Filip Janku [713-563-1930]

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients With HER2-positive Solid Tumors Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: NCI-2017-00491, SHRUS 1001

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

Phase: I

Therapy: pyrotinib

Location: United States

US States: FL, MA, MI, MO, NY, TN

US Contact: Dr. Ewa Matczak [609-423-2155 ext 215; ewa.matczak@hengruitherapeutics.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.

ERBB2 mutation (continued)

NCT03004534
A Presurgical Tissue-Acquisition Study to Evaluate Molecular Alterations in Human Breast Cancer Tissue Following Short-Term Exposure to the Androgen Receptor Antagonist ODM-201

Cancer type: Breast Cancer

Variant class: ERBB2 status

Other identifiers: EudraCT Number: 2016-004151-79, HC6-24-c 201058, TRIO030

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: I

Therapy: darolutamide

Locations: Canada, Germany, United States

US States: CA, FL

US Contact: Dr. Dennis Slamon [310-825-5193; dslamon@mednet.ucla.edu]

No NCT ID - see other identifier(s)
Precision 2: 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: ERBB2 mutation

Other identifiers: 1200.264, EudraCT Number: 2016-003411-34, Precision 2

Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV

Phase: II

Therapy: afatinib

Location: Belgium

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: ERBB2 mutation

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

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

Phase: II

Therapy: lapatinib

Location: France

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.

ERBB2 mutation (continued)

NCT02925234
A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: DRUP, EudraCT Number: 2015-004398-33, M15DRU, NL54757.031.16

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), First line, Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Netherlands

NCT03297606
Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 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: pertuzumab + trastuzumab

Location: Canada

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

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 2016-0430, NCI-2018-01218

Population segments: HER2 negative, HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapies: everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib

Location: United States

US State: TX

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

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.

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ERBB2 mutation (continued)

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: ERBB2 mutation

Other identifiers: 5209-CPK-1002, CTR20150792

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

Phase: I

Therapy: pirotinib

Location: China

NCT02435927
Phase I Study to Evaluate the Safety and Tolerability of ASLAN001 in Combination with Oxaliplatin and Capecitabine or Oxaliplatin and 5-FU with Leucovorin

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifier: ASLAN001-002SG

Population segments: Second line, Stage IV

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

BRAF mutation

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers

Cancer type: Breast Cancer

Variant class: BRAF aberration

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

Population segments: Adenocarcinoma, EGFR, FGFR, HER2 negative, KRAS, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

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.

BRAF mutation (continued)

NCT02925234
A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: DRUP, EudraCT Number: 2015-004398-33, M15DRU, NL54757.031.16

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), First line, Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapies: cobimetinib + vemurafenib, dabrafenib

Location: Netherlands

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

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

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: regorafenib

Location: United States

US States: AL, AZ, CA, FL, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, TX, UT, VA, WA

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

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: BRAF mutation

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

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

Exclusion criteria variant class: BRAF V600 mutation

Phase: II

Therapy: sorafenib

Location: France

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.

BRAF mutation (continued)

NCT03520075
A Phase I/II Study of the Safety, Pharmacokinetics, and Activity of ASTX029 in Subjects With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifier: ASTX029-01

Population segments: Second line, Stage III, Stage IV

Phase: I/II

Therapy: ASTX029

Location: United States

US States: CT, TX, VA

US Contact: Richard J. Morishige [925-560-2882; Richard.Morishige@astx.com]

NCT02639546
A Phase I/II, Multicenter, Open-Label, Dose-Escalation Study of The Safety And Pharmacokinetics of Cobimetinib In Pediatric And Young Adult Patients With Previously Treated Solid Tumors - iMATRIX Cobi

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: 15-524, 16-041, 2015-0929, CTRC#15-0005, DRKS00010690, EudraCT Number: 2014-004685-25, GO29665, iMATRIX Cobi, iMATRIXcobi, IRAS ID: 174562, NCI-2016-00541, NL52503.078.16

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

Phase: I/II

Therapy: cobimetinib

Locations: Canada, France, Germany, Israel, Italy, Spain, United Kingdom, United States

US States: AR, AZ, CA, FL, MA, NY, PA, TX

US Contact: Reference Study ID Number: GO29665 [888-662-6728; global-roche-genentech-trials@gene.com]

NCT03182673
A Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of SHR7390 Combined With SHR-1210 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: CTR20170611, SHR7390-SHR-1210-I-102-AST

Population segments: First line, Stage III, Stage IV

Phase: I

Therapy: camrelizumab + SHR7390

Location: China

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.

BRAF mutation (continued)

NCT03118817
A Single-arm, Open-label, Multi-center, Phase I Expansion Study Evaluating the Efficacy and Safety of HM95573 Monotherapy in Patients With BRAF, KRAS or NRAS Mutation-positive Solid Cancers

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifier: HM-RAFI-102

Population segments: (N/A), Line of therapy N/A

Phase: I

Therapy: HM-95573

Location: Republic of Korea

NCT03051035
A Phase I First-in-Human Study of KO-947 in Locally Advanced Unresectable or Metastatic, Relapsed and/or Refractory Non-Hematological Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 16-1101, 17-150, KO-ERK-001

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

Phase: I

Therapy: KO-947

Location: United States

US State: PA

US Contact: Kamn Lacroix [617-251-6535; medicalaffairs@kuraoncology.com]

NCT03284502
A Phase Ib, Open-label, Multicenter, Dose Escalation Study of the Safety, Tolerability, and Pharmacokinetics of Cobimetinib and HM95573 in Patients With Locally Advanced or Metastatic Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: RAF mutation

Other identifier: HM-RAFI-103

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

Phase: I

Therapy: cobimetinib + HM-95573

Location: Republic of Korea

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.

BRAF mutation (continued)

NCT02857270
A Phase I Study of an ERK1/2 Inhibitor (LY3214996) Administered Alone or in Combination With Other Agents in Advanced Cancer

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: 16419, EudraCT Number: 2016-001907-21, I8S-MC-JUAB, JUAB, NCI-2017-00039

Population segments: Second line, Stage III, Stage IV

Phase: I

Therapies: abemaciclib + LY3214996 , LY3214996 , LY3214996 + chemotherapy, LY3214996 + midazolam

Locations: Australia, France, United States

US States: FL, MA, TN, TX

US Contact: Eli Lilly and Company [877-285-4559]

NCT02711345
A Phase I Dose Finding Study of Oral LTT462 in Adult Patients With Advanced Solid Tumors Harboring MAPK Pathway Alterations

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: CLTT462X2101, EudraCT number: 2015-003614-24, JapicCTI-163207, NCI-2016-00539, NL57739.031.16

Population segments: First line, KRAS, Second line, Stage III, Stage IV

Phase: I

Therapy: LTT-462

Locations: Germany, Italy, Japan, Netherlands, Singapore, Spain, Switzerland, United States

US States: NY, TX

US Contact: Novartis Pharmaceuticals [888-669-6682; Novartis.email@novartis.com]

NCT02607813
A Phase I Dose Finding Study of Oral LXH254 in Adult Patients With Advanced Solid Tumors Harboring MAPK Pathway Alterations

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: 16-225, 2015-0913, CLXH254X2101, EudraCT Number: 2015-003421-33, NCI-2015-02280, NL55506.078.15, Nov RAFi (CLXH254X2101), REec-2016-2132, SNCTP000002708

Population segments: Second line, Stage III, Stage IV

Phase: I

Therapies: LXH254 , LXH254 + spartalizumab

Locations: Canada, France, Germany, Japan, Netherlands, Republic of Korea, Spain, Switzerland, United States

US States: NY, TX

US Contact: Novartis Pharmaceuticals [888-669-6682; Novartis.email@novartis.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.

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PIK3CA mutation

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, CBYL719XAU01T, CT772, LL14/02, PIKNIC, PIKNIC study

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER positive

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Location: Australia

NCT03056755
A Phase II, Multicenter, Open-label, Two-cohort, Non-comparative Study to Assess the Efficacy and Safety of Alpelisib Plus Fulvestrant or Letrozole in Patients With PIK3CA Mutant, Hormone Receptor (HR) Positive, HER2-negative Advanced Breast Cancer (aBC), Who Have Progressed on or After CDK 4/6 Inhibitor Treatment

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 18-076, BYLieve, BYLIEVE, CBYL719X2402, CTRI/2017/09/009687, EudraCT Number: 2016-004586-67, IEO 665, JapicCTI-173805, NCI-2017-01082

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

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

Phase: II

Therapies: alpelisib + fulvestrant, alpelisib + letrozole

Locations: Belgium, Canada, France, Germany, India, Israel, Italy, Japan, Netherlands, Singapore, Spain, United Kingdom, United States

US States: AZ, CA, FL, KS, KY, MA, MD, MI, MT, NM, NY, OH, TX, WA

US Contact: Novartis Pharmaceuticals [888-669-6682; Novartis.email@novartis.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.

PIK3CA mutation (continued)

NCT01723774
A Phase II Trial of Neoadjuvant PD 0332991, a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor, in Combination With Anastrozole in Women With Clinical Stage 2 or 3 Estrogen Receptor Positive and HER2 Negative Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 201301106, NCI-2012-02202, NeoPalAna

Population segments: Estrogen receptor positive, HER2 negative, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: ERBB2 negative, ER positive

Phase: II

Therapies: palbociclib + anastrozole, palbociclib + hormone therapy

Location: United States

US States: AZ, MN, MO

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

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

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

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

Phase: II

Therapy: everolimus

Location: United States

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

US Contact: Dr. Bryan Schneider [317-944-0920; bpschnei@iu.edu]

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers

Cancer type: Breast Cancer

Variant class: PIK3CA aberration

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

Population segments: Adenocarcinoma, EGFR, FGFR, HER2 negative, KRAS, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

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.

PIK3CA mutation (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: PIK3CA mutation

Other identifiers: 0C-14-10, 102084, 14-214, 14-430, 2014-0160, CR1322AZ, CSET 2365, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, PRO 09

Population segments: (N/A), Adenocarcinoma, Estrogen receptor positive, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive

Phase: I

Therapy: capivasertib

Locations: Canada, Denmark, France, Italy, Japan, Singapore, Spain, United States

US States: CA, CO, NY, OK, PA, TN, TX

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

NCT03006172
A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of GDC-0077 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 Hormone-Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 16-1556, EudraCT Number: 2016-003022-17, GO39374, NCI-2017-00262

Population segments: Estrogen receptor positive, HER2 negative, Line of therapy N/A, Progesterone receptor positive, Stage III, Stage IV

Phase: I

Therapy: GDC-0077

Locations: Canada, France, Spain, United Kingdom, United States

US States: MA, NY, TN

US Contact: Reference Study ID Number: GO39374 [888-662-6728; global-roche-genentech-trials@gene.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.

PIK3CA mutation (continued)

NCT03006172
A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of GDC-0077 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 Hormone-Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 16-1556, EudraCT Number: 2016-003022-17, GO39374, NCI-2017-00262

Population segments: Estrogen receptor positive, HER2 negative, Line of therapy N/A, Progesterone receptor positive, Stage III, Stage IV

Other inclusion criteria: ERBB2 negative, Hormone receptor positive

Phase: I

Therapies: GDC-0077 + fulvestrant, GDC-0077 + letrozole, GDC-0077 + palbociclib + letrozole

Locations: Canada, France, Spain, United Kingdom, United States

US States: MA, NY, TN

US Contact: Reference Study ID Number: GO39374 [888-662-6728; global-roche-genentech-trials@gene.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: Breast Cancer

Variant class: PIK3CA mutation

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

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, KRAS, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER positive

Phase: I

Therapies: palbociclib + pictilisib + fulvestrant, palbociclib + taselisib + fulvestrant

Location: 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

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, KRAS, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ER negative

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Location: United Kingdom

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.

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PIK3CA mutation (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

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, KRAS, Stage III, Stage IV, Triple receptor negative

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

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Location: 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: PIK3CA mutation

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

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

Phase: II

Therapy: everolimus

Location: France

NCT02688881
Study to Evaluate the Safety and Efficacy of Sirolimus, in Subject With Refractory Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 2016-02-052, KCT0002997, SMC 2016-02-052-001

Population segments: (N/A), Second line

Phase: II

Therapy: sirolimus

Location: Republic of Korea

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.

PIK3CA mutation (continued)

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA aberration

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-C1, EAY131-C2, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-J, EAY131-L, EAY131-M, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-W, EAY131-X, EAY131-Y, EAY131-Z1A, EAY131-Z1B, EAY131-Z1C, EAY131-Z1D, EAY131-Z1E, EAY131-Z1F, EAY131-Z1G, EAY131-Z1H, EAY131-Z1I, EAY131-Z1J, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH

Population segments: (N/A), Aggressive, Classical, Fourth line or greater, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line, Stage III, Stage IV, Third line

Phase: II

Therapy: copanlisib

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

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

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

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.

PIK3CA mutation (continued)

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD6738 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 1508016363, 16-314, NCI-2016-00922, OLAPCO, VICCMD1672

Population segments: First line, Second line, Stage IV

Phase: II

Therapy: capivasertib + olaparib

Location: United States

US States: CT, MA, OH, TN

US Contact: Manuel Avedissian [203-737-3669; manuel.avedissian@yale.edu]

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: 0C-14-10, 102084, 14-214, 14-430, 2014-0160, CR1322AZ, CSET 2365, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, PRO 09

Population segments: (N/A), Adenocarcinoma, Estrogen receptor positive, Fourth line or greater, HER2 positive, Hormone refractory, Second line, Stage III, Stage IV, Third line

Phase: I

Therapy: capivasertib

Locations: Canada, Denmark, France, Italy, Japan, Singapore, Spain, United States

US States: CA, CO, NY, OK, PA, TN, TX

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

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: 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

Therapy: gedatolisib + palbociclib

Location: United States

US State: MA

US Contact: Dr. Nicole Chau [617-632-3090]

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.

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PIK3CA mutation (continued)

NCT02124148
A Phase Ib Trial of LY2606368 in Combination With Chemotherapy or Targeted Agents in Advanced and/or Metastatic Tumors

Cancer type: Unspecified Cancer

Variant class: PIK3CA mutation

Other identifiers: 15295, 2014-0193, I4D-MC-JTJF, NCI-2014-01348

Population segments: Second line, Stage III, Stage IV

Phase: I

Therapy: LY-3023414 + prexasertib

Location: United States

US States: FL, OK, TN, TX

US Contact: Eli Lilly and Company [877-285-4559]

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

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, KRAS, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Location: United Kingdom

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.

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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.

ERBB2 mutation

Variant Class	Evidence Items
ERBB aberration	0
↳ ERBB2 status	2
↳ ERBB2 aberration	3
↳ ERBB2 mutation status	0
↳ ERBB2 mutation	19

BRAF mutation

Variant Class	Evidence Items
RAS/RAF/MEK/ERK pathway	5
↳ RAS/RAF/MEK/ERK mutation	0
↳ RAF mutation	1
↳ BRAF mutation status	0
↳ BRAF mutation	8
↳ RAF aberration	0
↳ BRAF aberration	1
↳ BRAF mutation status	0
↳ BRAF mutation	8
↳ RAF mutation	1
↳ BRAF mutation status	0
↳ BRAF mutation	8

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.

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Evidence Summary by Variant Class (continued)

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.

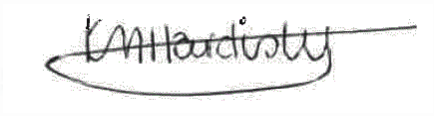
PIK3CA mutation

Variant Class	Evidence Items
PI3K/AKT/MTOR pathway	1
↳ PIK3CA aberration	4
↳ PIK3CA mutation status	0
↳ PIK3CA mutation	15

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.

Report Authorised by

Signed



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