[Oncofocus] Patient Test Report

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Surname		**Requesting clinician**	
Forename			
DOB		**Date requested**	
Gender	Female		
Histology #		**Tumour %**	70
Primary site	Breast	**Tumour % (macrodissected)**	
Tumour subtype	Adenocarcinoma		
Tissue type	Liver		

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. 167 genes were targeted covering 977 unique coding hot spots, 281 fusions and 19 CNV genes.

An ERBB2 variant of unknown clinical significance has been identified and classified as likely pathogenic.
9 clinical trials for ERBB2 mutations in breast cancer are listed, however this specific variant is not referenced in eligibility criteria.

In light of the broad range of potential therapies identified, alternate allele frequencies have been included in the report.

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		Alt allele freq	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
BRAF	p.(V600E)	c.1799T>A	5%	○ (5)	○ (5)	○ (5)	⚠ (11)	● (21)
PIK3CA	p.(G1049R)	c.3145G>C	58%	✖	✖	✖	✖	● (17)
ERBB2	p.(G727A)	c.2180G>C	39%	✖	✖	✖	○ (2)	● (9)

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'. Copy number variants of a >5% confidence value of ≥4 after normalisation are classified as amplified. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control. Assay sensitivity and positive predictive value is 99% when these thresholds are met. 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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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

BRAF p.(V600E) c.1799T>A

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
vemurafenib	○	○	✖	○	● (I)
cobimetinib + vemurafenib	○	○	✖	○	✖
dabrafenib	○	○	✖	○	✖
dabrafenib + trametinib	○	○	✖	○	✖
trametinib	○	○	✖	○	✖
ipilimumab	✖	✖	○	○	✖
nivolumab	✖	✖	○	○	✖
pembrolizumab	✖	✖	○	○	✖
BRAF inhibitor	✖	✖	○	✖	✖
BRAF inhibitor + MEK inhibitor	✖	✖	○	✖	✖
ipilimumab + nivolumab	✖	✖	✖	○	✖
cetuximab	✖	✖	✖	⊘	✖
panitumumab	✖	✖	✖	⊘	✖
erlotinib, pertuzumab + trastuzumab, vemurafenib, vismodegib	✖	✖	✖	✖	● (II)
binimetinib + encorafenib, binimetinib + encorafenib + ribociclib	✖	✖	✖	✖	● (I/II)
cetuximab + vemurafenib + chemotherapy	✖	✖	✖	✖	● (I/II)
LNP3794	✖	✖	✖	✖	● (I/II)
NKTR-214	✖	✖	✖	✖	● (I/II)
PLX-8394	✖	✖	✖	✖	● (I/II)
AB-024	✖	✖	✖	✖	● (I)
alpelisib + binimetinib	✖	✖	✖	✖	● (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.

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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

BRAF p.(V600E) c.1799T>A (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
BAL-3833	✖	✖	✖	✖	● (I)
BGB-283	✖	✖	✖	✖	● (I)
BVD-523	✖	✖	✖	✖	● (I)
crizotinib + dasatinib	✖	✖	✖	✖	● (I)
crizotinib + vemurafenib, sorafenib + vemurafenib	✖	✖	✖	✖	● (I)
dabrafenib + midazolam + rosuvastatin calcium	✖	✖	✖	✖	● (I)
dabrafenib + rabeprazole sodium + rifampicin	✖	✖	✖	✖	● (I)
dabrafenib, dabrafenib + trametinib	✖	✖	✖	✖	● (I)
everolimus + vemurafenib, temsirolimus + vemurafenib	✖	✖	✖	✖	● (I)
RO-5126766	✖	✖	✖	✖	● (I)
vemurafenib + chemotherapy	✖	✖	✖	✖	● (I)
vemurafenib + rifampicin	✖	✖	✖	✖	● (I)

PIK3CA p.(G1049R) c.3145G>C

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
sirolimus	✖	✖	✖	✖	● (IV)
alpelisib + fulvestrant, fulvestrant + placebo	✖	✖	✖	✖	● (III)
fulvestrant + placebo, taselisib + fulvestrant	✖	✖	✖	✖	● (III)
alpelisib	✖	✖	✖	✖	● (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)

PIK3CA p.(G1049R) c.3145G>C (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
alpelisib + letrozole, buparlisib + letrozole, letrozole + placebo	✖	✖	✖	✖	● (II)
AZD-2014 + olaparib, AZD-5363 + olaparib, MK-1775 + olaparib, olaparib	✖	✖	✖	✖	● (II)
letrozole + placebo, taselisib + letrozole	✖	✖	✖	✖	● (II)
AZD-5363 + chemotherapy	✖	✖	✖	✖	● (I/II)
taselisib, taselisib + fulvestrant, taselisib + letrozole	✖	✖	✖	✖	● (I/II)
alpelisib + binimetinib	✖	✖	✖	✖	● (I)
alpelisib + infigratinib	✖	✖	✖	✖	● (I)
ARQ-092	✖	✖	✖	✖	● (I)
AZD-5363	✖	✖	✖	✖	● (I)
AZD-8835, AZD-8835 + fulvestrant	✖	✖	✖	✖	● (I)
copanlisib	✖	✖	✖	✖	● (I)
MSC-2363318A	✖	✖	✖	✖	● (I)
palbociclib + pictilisib, palbociclib + taselisib	✖	✖	✖	✖	● (I)

ERBB2 mutation p.(G727A) c.2180G>C

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
afatinib	✖	✖	✖	○	✖
trastuzumab	✖	✖	✖	○	✖
alpelisib	✖	✖	✖	✖	● (II)
everolimus, lapatinib, nilotinib, pazopanib, sorafenib	✖	✖	✖	✖	● (II)
neratinib	✖	✖	✖	✖	● (II)
neratinib, neratinib + fulvestrant, neratinib + trastuzumab, neratinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
poziotinib	✖	✖	✖	✖	● (II)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)
MSC-2363318A	✖	✖	✖	✖	● (I)
pirotinib	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)

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Current EMA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

EMA information is current as of 2016-04-01. For the most up-to-date information, search www.ema.europa.eu/ema.

BRAF p.(V600E) c.1799T>A

○ cobimetinib + vemurafenib

Cancer type: Melanoma **Label as of:** 2016-02-12 **Variant class:** BRAF V600 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003960/WC500198563.pdf

○ dabrafenib + trametinib, trametinib

Cancer type: Melanoma **Label as of:** 2016-04-21 **Variant class:** BRAF V600 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002643/WC500169657.pdf

○ dabrafenib, dabrafenib + trametinib

Cancer type: Melanoma **Label as of:** 2015-11-20 **Variant class:** BRAF V600 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002604/WC500149671.pdf

○ vemurafenib

Cancer type: Melanoma **Label as of:** 2016-04-27 **Variant class:** BRAF V600 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002409/WC500124317.pdf

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Current US-FDA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-FDA information is current as of 2016-04-01. For the most up-to-date information, search www.fda.gov.

BRAF p.(V600E) c.1799T>A

○ cobimetinib + vemurafenib

Cancer type: Melanoma **Label as of:** 2015-11-10 **Variant class:** BRAF V600E mutation

Indications and usage:

COTELLIC™ is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

Limitation of Use: COTELLIC™ is not indicated for treatment of patients with wild-type BRAF melanoma.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206192s000lbl.pdf

○ dabrafenib + trametinib, trametinib

Cancer type: Melanoma **Label as of:** 2015-11-20 **Variant class:** BRAF V600E mutation

Indications and usage:

MEKINIST™ is a kinase inhibitor indicated, as a single agent or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA approved test.

Limitation of use: MEKINIST is not indicated for treatment of patients who have received prior BRAF-inhibitor therapy.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204114s004lbl.pdf

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BRAF p.(V600E) c.1799T>A (continued)

dabrafenib, dabrafenib + trametinib

Cancer type: Melanoma **Label as of:** 2015-11-20 **Variant class:** BRAF V600E mutation

Indications and usage:

- TAFINLAR is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
- TAFINLAR is indicated, in combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.

Limitation of Use: TAFINLAR is not indicated for treatment of patients with wild-type BRAF melanoma.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202806s004lbl.pdf

vemurafenib

Cancer type: Melanoma **Label as of:** 2015-08-11 **Variant class:** BRAF V600E mutation

Indications and usage:

ZELBORAF® is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Limitation of Use: ZELBORAF® is not indicated for treatment of patients with wild-type BRAF melanoma.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202429s008lbl.pdf

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Current ESMO Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

ESMO information is current as of 2016-03-04. For the most up-to-date information, search www.esmo.org.

BRAF p.(V600E) c.1799T>A

○ BRAF inhibitor

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Metastatic (preferred) or primary tumour (First and second line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cutaneous Melanoma [Ann Oncol (2015) 26 (suppl 5): v126-v132.]

○ BRAF inhibitor + MEK inhibitor

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Metastatic (preferred) or primary tumour (First and second line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cutaneous Melanoma [Ann Oncol (2015) 26 (suppl 5): v126-v132.]

○ ipilimumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Metastatic (preferred) or primary tumour (First and second line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cutaneous Melanoma [Ann Oncol (2015) 26 (suppl 5): v126-v132.]

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BRAF p.(V600E) c.1799T>A (continued)

nivolumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Metastatic (preferred) or primary tumour (First and second line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cutaneous Melanoma [Ann Oncol (2015) 26 (suppl 5): v126-v132.]

pembrolizumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Metastatic (preferred) or primary tumour (First and second line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Cutaneous Melanoma [Ann Oncol (2015) 26 (suppl 5): v126-v132.]

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Current US-NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-NCCN information is current as of 2016-03-04. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

BRAF p.(V600E) c.1799T>A

○ dabrafenib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** BRAF V600E mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 4.2016]

○ dabrafenib + trametinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** BRAF V600E mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 4.2016]

○ vemurafenib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** BRAF V600E mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 4.2016]

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BRAF p.(V600E) c.1799T>A (continued)

cobimetinib + vemurafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable (First line therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

dabrafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

dabrafenib + trametinib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy) (preferred)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

ipilimumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

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BRAF p.(V600E) c.1799T>A (continued)

nivolumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

trametinib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Disseminated disease (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

vemurafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

cobimetinib + vemurafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

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BRAF p.(V600E) c.1799T>A (continued)

dabrafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy, if not used as first-line and not of the same (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

dabrafenib + trametinib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy) (preferred)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

ipilimumab + nivolumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy)
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

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BRAF p.(V600E) c.1799T>A (continued)

nivolumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

pembrolizumab

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease (First-line therapy)
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

vemurafenib

Cancer type: Melanoma **Variant class:** BRAF V600 mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic or unresectable disease, Disease progression or Maximum clinical benefit from BRAF targeted therapy (Second-line or Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Melanoma [Version 2.2016]

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BRAF p.(V600E) c.1799T>A (continued)

cetuximab

Cancer type: Colorectal Cancer **Variant class:** BRAF V600 mutation

Summary:

NCCN Guidelines® do not contain a recommendation regarding BRAF V600 mutations and cetuximab in Colon Cancer, but include the following evidentiary statements:

- "Evidence increasingly suggest that BRAF V600E mutations makes response to panitumumab or cetuximab highly unlikely, as a single agent, or in combination with cytotoxic chemotherapy"

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 2.2016]

panitumumab

Cancer type: Colorectal Cancer **Variant class:** BRAF V600 mutation

Summary:

NCCN Guidelines® do not contain a recommendation regarding BRAF V600 mutations and panitumumab in Colon Cancer, but include the following evidentiary statements:

"Evidence increasingly suggest that BRAF V600E mutations makes response to panitumumab or cetuximab highly unlikely, as a single agent, or in combination with cytotoxic chemotherapy"

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 2.2016]

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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Current US-NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-NCCN information is current as of 2016-03-04. 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

○ afatinib

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 4.2016]

○ trastuzumab

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 4.2016]

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 Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-03-01. 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'.

BRAF p.(V600E) c.1799T>A

NCT02091141

My Pathway: An Open Label Phase IIa Study Evaluating Trastuzumab/ Pertuzumab, Erlotinib, Vemurafenib, and Vismodegib in Patients Who Have Advanced Solid Tumors With Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents

Cancer type: Unspecified Solid Tumor

Variant class: BRAF activating mutation

Other identifiers: 1403013519, 2014-0459, AAAN9701, ML28897, ML28897/PRO 02, ML28897PRO/02, My Pathway, TrialTroveID-205033

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

Exclusion criteria variant classes: EGFR exon 20 mutation, RAS mutation, ERBB2 amplification

Phase: II

Therapies: erlotinib, pertuzumab + trastuzumab, vemurafenib, vismodegib

Country: United States

US States: AR, AZ, CA, CO, FL, GA, IL, MD, MN, NC, ND, NY, OH, OK, OR, PA, SD, TN, TX, VA, WA

US Contact: Reference Study ID Number: ML28897 [888-662-6728; global.rochegenentechtrials@roche.com]

NCT01543698

A Phase Ib/II, Multicenter, Open-label, Dose Escalation Study of LGX818 in Combination With MEK162 and LEE-011 in Adult Patients With BRAF V600-Dependent Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: 12-193, 2012-0238, CMEK162X2110, EudraCT Number:2011-005875-17, J12117, MCC#17318, NCI-2012-00964, TrialTroveID-163520

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

Phase: I/II

Therapies: binimetinib + encorafenib, binimetinib + encorafenib + ribociclib

Countries: Australia, Belgium, Canada, France, Italy, Spain, Switzerland

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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BRAF p.(V600E) c.1799T>A (continued)

NCT01787500
A Phase I Trial of Vemurafenib in Combination With Cetuximab and Irinotecan in Patients with BRAF V600 Mutant Advanced Solid Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: 2012-0748, NCI-2013-00541, TrialTroveID-181751

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

Other inclusion criteria: KRAS wild type

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

Phase: I/II

Therapy: cetuximab + vemurafenib + chemotherapy

Country: United States

US State: TX

US Contact: Dr. David S. Hong [713-593-1930]

NCT02428712
A Phase I/IIa Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients With Advanced, Unresectable Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF activating mutation

Other identifiers: PLX120-03, TrialTroveID-256645

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

Phase: I/II

Therapy: PLX-8394

Country: United States

US States: AZ, MI, TX, UT

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

No NCT ID - see other identifier(s)
A Phase I/II Study of LNP3794 in Patients with Advanced Solid Tumors having RAS/BRAF Mutations

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifier: TrialTroveID-250171

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

Phase: I/II

Therapy: LNP3794

Country: 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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BRAF p.(V600E) c.1799T>A (continued)

No NCT ID - see other identifier(s)
A Phase 1/2, Open-Label, Multicenter, Dose Escalation and Dose Expansion Study of NKTR-214 in Subjects with Locally Advanced or Metastatic Solid Tumor Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 2015-0573, TrialTroveID-258750

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

Phase: I/II

Therapy: NKTR-214

Country: United States

US State:

US Contact: MD Anderson Cancer Center For Clinical Trial Enrollment [713-792-2921]

NCT02082665
An Open-label Phase I Study to Evaluate the Effects of Dabrafenib (GSK2118436) on the Single Dose Pharmacokinetics of an OATP1B1/1B3 Substrate and of a CYP3A4 Substrate in Subjects With BRAF V600 Mutation Positive Tumors

Cancer type: Unspecified Cancer

Variant class: BRAF V600 mutation

Other identifiers: 200919, TrialTroveID-204485

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

Phase: I

Therapy: dabrafenib + midazolam + rosuvastatin calcium

Country: Spain

NCT01954043
An Open-label Study to Evaluate the Effects of a Potent CYP3A4 Inducer and the Effects of a pH Elevating Agent on the Repeat Dose Pharmacokinetics of Dabrafenib (GSK2118436) in Subjects With BRAF V600 Mutation Positive Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: 170049, 200072, Euctr Number: 2014-003093-17, TrialTroveID-194828

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

Phase: I

Therapy: dabrafenib + rabeprazole sodium + rifampicin

Countries: Australia, United States

US States: TX, WA

US Contact: US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.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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BRAF p.(V600E) c.1799T>A (continued)

NCT01767623
An Open Label, Phase I Study to Evaluate the Impact of Severe Hepatic Impairment on the Pharmacokinetics and Safety of Vemurafenib in BRAF V600 mutation Positive Cancer Patients

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: 1803-7, EudraCT Number: 2012-003820-18, GO28053, IRAS ID: 120756, PER-052-13, TrialTroveID-152167

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

Phase: I

Therapy: vemurafenib

Countries: Australia, Israel, Turkey

NCT02441465
A Phase I, Open-Label, Absolute Bioavailability Study of Vemurafenib in Patients With BRAF^V600 Mutation-Positive Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: EudraCT Number: 2013-004144-34, GO28395, TrialTroveID-257287

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

Phase: I

Therapy: vemurafenib

Country: Hungary

NCT01765543
A Phase I, Open-Label, Multicenter, Three-Period, One-Sequence Study To Investigate The Effect Of Rifampin On The Pharmacokinetics Of A Single Oral Dose Of 960 Mg Of Vemurafenib

Cancer type: Unspecified Solid Tumor

Variant class: BRAF V600 mutation

Other identifiers: EudraCT Number: 2012-003142-33, GO28052, TrialTroveID-179892

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

Phase: I

Therapy: vemurafenib + rifampicin

Countries: Brazil, Croatia, Egypt, South Africa, United States

US States: AR, TX

US Contact: Reference Study ID Number: GO28052 [888-662-6728; global.rochegenentechtrials@roche.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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BRAF p.(V600E) c.1799T>A (continued)

NCT01877811
An Open-Label, Phase 1/1b, Single-Agent Study of RXDX-105 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: C32496/1105, NCI-2013-01795, RXDX-105-01, TrialTroveID-167849

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

Other inclusion criteria: KRAS wild type

Exclusion criteria variant classes: RET V804 mutation, EGFRi sensitizing mutation

Phase: I

Therapy: AB-024

Country: United States

US States: CA, FL, MI, MO, PA

US Contact: Teva US Medical Information [800-896-5855]

NCT01449058
A Phase Ib Open-label, Multi-center, Dose Escalation and Expansion Study of Orally Administered MEK162 Plus BYL719 in Adult Patients With Selected Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant classes: BRAF mutation & PIK3CA mutation

Other identifiers: 11-490, 15-039, 2013-0813, CMEK162X2109, CSET 1840, EudraCT Number: 2011-002578-21, HCI 53590, MSKCC-11-117, NCI-2012-00874, Novartis#CMEK162X2109, RECF2113, TrialTroveID-154495

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

Phase: I

Therapy: alpelisib + binimetinib

Countries: Australia, France, Spain, Switzerland, United States

US States: CA, IL, MA, NY, UT

US Contact: Novartis Pharmaceuticals [862-778-8300]

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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BRAF p.(V600E) c.1799T>A (continued)

NCT02437227
A Phase 1, First in Man, Dual Centre, Open-label Dose Escalation Study With Expansion to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of CCT3833 (BAL3833), a panRAF Inhibitor, Given Orally in Patients With Advanced Solid Tumours, Including Metastatic Melanoma

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 4232, PanRAF, TrialTroveID-257046

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

Phase: I

Therapy: BAL-3833

Country: United Kingdom

No NCT ID - see other identifier(s)
A Phase Ib, Multi-Center Study to Evaluate the Efficacy of BGB-283 in Patients with Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifier: TrialTroveID-261285

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

Phase: I

Therapy: BGB-283

Countries: Australia, New Zealand

NCT02610361
A Phase IA/IB, Open-Label, Multiple-Dose, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics and Preliminary Antitumor Activities of the B RAF Inhibitor BGB 283 in Subjects With Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: ACTRN12614001176651, BGB-283-AU-001, TrialTroveID-268375

Population segments: First line, Stage III, Stage IV

Phase: I

Therapy: BGB-283

Countries: Australia, New Zealand

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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BRAF p.(V600E) c.1799T>A (continued)

NCT01781429
Phase I Dose-Escalation, Safety, Pharmacokinetic and Pharmacodynamic Study of BVD-523 in Patients With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 13-010, 13-254, 2013-0574, AAAP2107, BVD-523-01, REFMAL 286 IST, TrialTroveID-180584, VICCPHI1375

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

Phase: I

Therapy: BVD-523

Country: United States

US States: CA, CT, FL, MA, MO, NY, TN, TX

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

NCT01744652
A Phase I Trial of Dasatinib in Combination With Crizotinib in Patients With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 2012-0721, NCI-2013-00071, TrialTroveID-178941

Population segments: Aggressive, Classical, Hormone refractory, Indolent, Metastatic, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage IV, Unresectable

Phase: I

Therapy: crizotinib + dasatinib

Country: United States

US State: TX

US Contact: Dr. David S. Hong [800-392-1611]

NCT01531361
A Phase I Trial of Sorafenib (CRAF, BRAF, KIT, RET, VEGFR, PDGFR Inhibitor) or Crizotinib (MET, ALK, ROS1 Inhibitor) in Combination With Vemurafenib (BRAF Inhibitor) in Patients With Advanced Malignancies

Cancer type: Unspecified Cancer

Variant class: BRAF mutation

Other identifiers: 2011-1183, NCI-2012-00217, TrialTroveID-162168

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

Phase: I

Therapies: crizotinib + vemurafenib, sorafenib + vemurafenib

Country: United States

US State: TX

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

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 p.(V600E) c.1799T>A (continued)

NCT01231594
A Rollover Study to provide Continued Treatment with GSK2118436 to Subjects with BRAF Mutation-Positive Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 114144, 12-016, 2010-0801, 44629, BRF114144, Eudra CT Number: 2011-000883-83, F14020, HCI 44629, IRAS ID 95276, NCI-2011-02757, OSU-11024, REFMAL 223, TrialTroveID-137250, VICCMEL1209

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

Phase: I

Therapies: dabrafenib, dabrafenib + trametinib

Countries: Australia, Italy, Spain, United Kingdom, United States

US States: AZ, CA, FL, MI, NY, OH, OK, PA, SC, TN, TX, UT, WA

US Contact: US GSK Clinical Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

NCT01596140
A Phase I Dose-Escalation Study of the BRAF Inhibitor Vemurafenib (Zelboraf) in Combination With an mTOR Inhibitor, Everolimus (Afinitor) or Temsirolimus (Torisel), in Subjects With Advanced Cancer

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 2012-0153, TrialTroveID-167369

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

Phase: I

Therapies: everolimus + vemurafenib, temsirolimus + vemurafenib

Country: United States

US State: TX

US Contact: Dr. Vivek Subbiah [713-794-1226]

NCT02407509
A Phase I Trial of RO5126766 (a Dual RAF/MEK Inhibitor) Exploring Intermittent, Oral Dosing Regimens in Patients With Solid Tumours or Multiple Myeloma

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: CCR3808, DDU RAF/MEK, EudraCT Number: 2012-001040-22, TrialTroveID-206542

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

Phase: I

Therapy: RO-5126766

Country: 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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BRAF p.(V600E) c.1799T>A (continued)

NCT01636622
Phase I Study of the Combination of Vemurafenib With Carboplatin and Paclitaxel in Patients With Advanced Malignancy

Cancer type: Unspecified Solid Tumor

Variant class: BRAF mutation

Other identifiers: 2012-0394, NCI-2012-01221, TrialTroveID-171156

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

Phase: I

Therapy: vemurafenib + chemotherapy

Country: United States

US State: TX

US Contact: MD Anderson Cancer Center [800-392-1611]

PIK3CA p.(G1049R) c.3145G>C

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, EudraCT Number: 2015-000340-42, NCI-2015-01171, SOLAR-1, TrialTroveID-257091

Population segments: First line, 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: Austria, Belgium, Canada, Czech Republic, France, Germany, Greece, Hong Kong, Hungary, Israel, Italy, Japan, Lebanon, Netherlands, Republic of Korea, Spain, Sweden, Taiwan, Thailand, United States

US States: CA, FL, IL, IN, KS, LA, MA, MD, MI, MO, NJ, OH, SD, TN, TX, UT, VA, WA

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

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 p.(G1049R) c.3145G>C (continued)

NCT02313948

A Phase III, Double-blind, Placebo Controlled, Randomized Study of Taselisib plus Fulvestrant Versus Placebo Plus Fulverstrant 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, 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, taselisib + fulvestrant

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

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

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

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: LL14/02, PIKNIC, TrialTroveID-261995

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

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Country: Australia

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 p.(G1049R) c.3145G>C (continued)

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, 14752, 20132066, ABCSG-40, BRTA2201, CBYL719A2201, CTMS# 15-2039, EudraCT Number: 2013-001862-41, J13178, 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, Lebanon, Netherlands, Spain, United States

US States: AL, AR, CA, GA, MA, MD, MN, NC, NJ, OR, TN, TX, VA, WA

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

NCT02273973

A Phase II Randomized, Double-Blind, Parallel Cohort Study of Neoadjuvant Letrozole + GDC-0032 Versus Letrozole + Placebo in Post-Menopausal Women With ER+/HER2- Primary Breast Cancer

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 15-020, 2014-0580, ABCSG 38, BIG-3-13, EORTC-1319-BCG, EORTC-1319-BCG - Lorelei, EudraCT Number: 2013-000568-28, GO28888, IBCSG 46-13 LORELEI, 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.rochegenentechtrials@roche.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 p.(G1049R) c.3145G>C (continued)

NCT01625286
A Phase I/II Study of AZD5363 Combined With Paclitaxel in Patients With Advanced or Metastatic Breast Cancer. Comprising a Safety Run-In and a Placebo-controlled Randomised Expansion in ER+ve Patients Stratified by PIK3CA Mutation Status

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: 12/LO/0803, 15/P/019, 99497, B214, BEECH, CR1421AZ, D3610C00002, EudraCT Number: 2011-006312-31, JapicCTI-142468, NL40149.031.12, PER-092-13, RD12/0036/0006, RECF1937, TrialTroveID-170030

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

Other inclusion criteria: ERBB2 wild type, ER positive

Phase: I/II

Therapy: AZD-5363 + chemotherapy

Countries: Canada, Czech Republic, France, Japan, Mexico, Peru, Republic of Korea, Singapore, Spain, United Kingdom

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

Therapies: taselisib, taselisib + fulvestrant, taselisib + letrozole

Countries: Canada, Spain, United States

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

US Contact: Reference Study ID Number: PMT4979g [888-662-6728; global.rochegenentechtrials@roche.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 p.(G1049R) c.3145G>C (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: 102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773

Population segments: 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, France, Italy, Japan, Netherlands, Singapore, Spain, United Kingdom, United States

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

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

NCT02260661
A phase I, open-label, multicentre, dose-escalation study to investigate the safety and pharmacokinetics of AZD8835 in patients with advanced solid tumours

Cancer type: Breast Cancer

Variant class: PIK3CA mutation

Other identifiers: D6140C00001, NCI-2015-01860, TrialTroveID-218498

Population segments: First line, HER2 negative, Stage III, Stage IV

Other inclusion criteria: ERBB2 wild type, ER positive

Phase: I

Therapies: AZD-8835, AZD-8835 + fulvestrant

Countries: United Kingdom, United States

US States: CO, TN

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

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PIK3CA p.(G1049R) c.3145G>C (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

NCT02155582
A Phase I Pharmacodynamic Study of Copanlisib (BAY 80-6946) as Monotherapy in Patients with Non-Hodgkin`s Lymphoma and Solid Tumors

Cancer type: Breast Cancer

Variant class: PIK3CA aberration

Other identifiers: 16790, EudraCT Number: 2013-004746-42, TrialTroveID-210261

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Peripheral T-cell lymphoma (PTCL), Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: I

Therapy: copanlisib

Countries: Belgium, France

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: IV

Therapy: sirolimus

Country: 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 p.(G1049R) c.3145G>C (continued)

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

Therapies: AZD-2014 + olaparib, AZD-5363 + olaparib, MK-1775 + olaparib, olaparib

Country: United States

US State: CT

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

NCT01449058
A Phase Ib Open-label, Multi-center, Dose Escalation and Expansion Study of Orally Administered MEK162 Plus BYL719 in Adult Patients With Selected Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant classes: BRAF mutation & PIK3CA mutation

Other identifiers: 11-490, 15-039, 2013-0813, CMEK162X2109, CSET 1840, EudraCT Number: 2011-002578-21, HCI 53590, MSKCC-11-117, NCI-2012-00874, Novartis#CMEK162X2109, RECF2113, TrialTroveID-154495

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

Phase: I

Therapy: alpelisib + binimetinib

Countries: Australia, France, Spain, Switzerland, United States

US States: CA, IL, MA, NY, UT

US Contact: Novartis Pharmaceuticals [862-778-8300]

NCT01928459
A Phase Ib, Open-label Study of Oral BGJ398 in Combination with Oral BYL719 in Adult Patients with Select Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: 13-246, CBGJ398X2102, CT610, CTBE2014000264, EudraCT Number: 2013-001018-14, NCI-2013-01763, NL47080.031.13, SAKK 69/13, TrialTroveID-192837

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

Other inclusion criteria: FGFR2 wild type, FGFR1 wild type, FGFR3 wild type

Phase: I

Therapy: alpelisib + infigratinib

Countries: Australia, Belgium, France, Germany, Italy, Republic of Korea, Spain, Switzerland, United States

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

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

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 p.(G1049R) c.3145G>C (continued)

NCT01473095
A Phase I Dose Escalation Study of ARQ 092 in Adult Subjects With Advanced Solid Tumors and Recurrent Malignant Lymphoma

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifiers: ARQ 092-101, NCI-2015-00308, TrialTroveID-156858

Population segments: Aggressive, Classical, Follicular lymphoma (FL), Hormone refractory, Indolent, Localized, Locally advanced, Metastatic, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV

Phase: I

Therapy: ARQ-092

Country: United States

US States: AZ, FL, GA, IN, TX

US Contact: ArQule, Inc. [781-994-0300; ClinicalTrials@arqule.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: PIK3CA aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, 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]

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 Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-03-01. 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'.

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: LL14/02, PIKNIC, TrialTroveID-261995

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

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Country: 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, TrialTroveID-214673

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

Phase: II

Therapy: neratinib

Country: Belgium

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, 201209135, DFCI: 13-237, TrialTroveID-173584, UAB1326, WASHU 201209135

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

Other inclusion criteria: ER negative

Phase: II

Therapies: neratinib, neratinib + fulvestrant, neratinib + trastuzumab, neratinib + trastuzumab + fulvestrant

Countries: Canada, United States

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

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

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)

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

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 2014-11-078, TrialTroveID-264275

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

Phase: II

Therapy: poziotinib

Country: Republic of Korea

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, TrialTroveID-210119

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

Other inclusion criteria: ER positive, PR positive/negative

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Country: United States

US State: TX

US Contact: Dr. Jennifer J. Wheler [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 Who Failed Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: SHRUS 1001, TrialTroveID-261429

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

Phase: I

Therapy: pyrotinib

Country: United States

US State: TX

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

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)

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, TrialTroveID-200294

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

Exclusion criteria variant class: BRAF V600 mutation

Phase: II

Therapies: everolimus, lapatinib, nilotinib, pazopanib, sorafenib

Country: France

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, TrialTroveID-269399

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

Phase: I

Therapy: pirotinib

Country: China

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: ERBB2 aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, 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]

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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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.

BRAF p.(V600E) c.1799T>A

Variant Class	Evidence Items
RAF mutation	0
↳ BRAF mutation	14
↳ BRAF exon 15 mutation	0
↳ BRAF V600 mutation	32
↳ BRAF V600E mutation	7
↳ BRAF activating mutation	2
↳ BRAF V600 mutation	32
↳ BRAF V600E mutation	7

PIK3CA p.(G1049R) c.3145G>C

Variant Class	Evidence Items
PIK3CA aberration	2
↳ PIK3CA mutation	14

ERBB2 mutation

Variant Class	Evidence Items
ERBB2 aberration	1
↳ ERBB2 mutation	10

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Report Signed by		Report Checked by	
			
Clinical Scientist	☑	BMS	☐
Pathologist	☐	BMS (Senior)	☑
BMS (Senior)	☐		

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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.

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(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.

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