[Oncofocus] Patient Test Report

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ONC17
Surname
Forename
DOB
Gender
Histology #
Primary site
Tumour subtype
Tissue Type

Requester
Contact details
Date requested

Tumour %
Tumour %
(macrodissected)

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.

237 genes were targeted using 2530 unique amplicons covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are linked to 690 anti-cancer targeted therapies.

The following actionable variants were detected:

Sample Cancer Type: Breast Cancer

Variant 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

Gene Variant	EMA	FDA	ESMO	NCCN	Clinical Trials
EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC	○ (4)	○ (3)	○ (4)	⚠ (7)	● (10)
TP53 p.(L194R) c.581T>G	✖	✖	✖	✖	● (7)
EGFR amplification	✖	✖	✖	✖	● (7)

EMA: European Medicine Agency, **FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence.

Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value(PPV) of 92%. 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 >20 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.

Referring pathology dept:

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.

Disclaimer: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2017.11(006).

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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

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
erlotinib	○	○	○	○	● (II)
afatinib	○	○	○	○	✖
gefitinib	○	○	○	○	✖
bevacizumab + erlotinib	○	✖	○	✖	✖
afatinib + cetuximab	✖	✖	✖	○	✖
alectinib	✖	✖	✖	⊘	✖
ceritinib	✖	✖	✖	⊘	✖
crizotinib	✖	✖	✖	⊘	✖
afatinib, osimertinib	✖	✖	✖	✖	● (II)
alpelisib	✖	✖	✖	✖	● (II)
cetuximab	✖	✖	✖	✖	● (II)
erlotinib + chemotherapy	✖	✖	✖	✖	● (II)
poziotinib	✖	✖	✖	✖	● (II)
pirotinib	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
epitinib	✖	✖	✖	✖	● (I)
varlitinib + chemotherapy	✖	✖	✖	✖	● (I)

TP53 p.(L194R) c.581T>G

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

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

Referring pathology dept:

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Relevant Therapy Summary (continued)

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

TP53 p.(L194R) c.581T>G (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
olaparib + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (II)
VX-970, VX-970 + chemotherapy	✖	✖	✖	✖	● (I/II)
LY3143921	✖	✖	✖	✖	● (I)
pembrolizumab + p53MVA	✖	✖	✖	✖	● (I)
SGT-53, SGT-53 + chemotherapy	✖	✖	✖	✖	● (I)

EGFR amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
alpelisib	✖	✖	✖	✖	● (II)
cetuximab	✖	✖	✖	✖	● (II)
gefitinib	✖	✖	✖	✖	● (II)
poziotinib	✖	✖	✖	✖	● (II)
pirotinib	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
varlitinib + chemotherapy	✖	✖	✖	✖	● (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 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 2017-09-25. For the most up-to-date information, search www.ema.europa.eu/ema.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

○ **afatinib**

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2017-08-15 **Variant class:** EGFR exon 19 deletion

Reference:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002280/WC500152392.pdf

○ **bevacizumab + erlotinib**

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2017-07-21 **Variant class:** EGFR exon 19 deletion

Reference:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000582/WC500029271.pdf

○ **erlotinib**

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2017-01-12 **Variant class:** EGFR exon 19 deletion

Reference:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000618/WC500033994.pdf

○ **gefitinib**

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2017-05-29 **Variant class:** EGFR exon 19 deletion

Reference:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001016/WC500036358.pdf

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 FDA Information

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

FDA information is current as of 2017-09-25. For the most up-to-date information, search www.fda.gov.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

○ afatinib

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2016-10-04 **Variant class:** EGFR exon 19 deletion

Indications and usage:

GILOTRIF® is a kinase inhibitor indicated for:

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

Limitation of Use: Safety and efficacy of GILOTRIF® were not established in patients whose tumors have other EGFR mutations

- Treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201292s010lbl.pdf

○ erlotinib

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2016-10-18 **Variant class:** EGFR exon 19 deletion

Indications and usage:

TARCEVA® is a kinase inhibitor indicated for:

- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Limitations of Use:

- Safety and efficacy of TARCEVA® have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- TARCEVA® is not recommended for use in combination with platinum-based chemotherapy.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021743s025lbl.pdf

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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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

gefitinib

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2015-07-13 **Variant class:** EGFR exon 19 deletion

Indications and usage:

IRESSA® is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of IRESSA® have not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206995s000lbl.pdf

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 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 2017-09-01. For the most up-to-date information, search www.esmo.org.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

○ afatinib

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Stage IV Non-Squamous Cell Carcinoma; PS 0-4 (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Ann Oncol (2016) 27 (suppl 5): v1-v27.]

○ erlotinib

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Stage IV Non-Squamous Cell Carcinoma; PS 0-4 (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Ann Oncol (2016) 27 (suppl 5): v1-v27.]

○ gefitinib

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Stage IV Non-Squamous Cell Carcinoma; PS 0-4 (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Ann Oncol (2016) 27 (suppl 5): v1-v27.]

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

bevacizumab + erlotinib

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Stage IV Non-Squamous Cell Carcinoma (First-line therapy)
- Stage IV Non-Squamous Cell Carcinoma; If bevacizumab given previously (Maintenance therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Ann Oncol (2016) 27 (suppl 5): v1-v27.]

erlotinib

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

ESMO Recommendation category: I, B

Population segment (Line of therapy):
- Stage IV Non-Squamous Small Cell Lung Cancer; PS 0-1; Partial response or stable disease (Maintenance therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Ann Oncol (2016) 27 (suppl 5): v1-v27.]

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Current NCCN Information

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

NCCN information is current as of 2017-09-01. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

○ afatinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered prior to first-line chemotherapy (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

○ erlotinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered prior to first-line chemotherapy (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

○ gefitinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered prior to first-line chemotherapy (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

afatinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered during first-line chemotherapy; Interrupt or complete planned chemotherapy, including maintenance therapy (First-line therapy)
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Progression after first-line therapy (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

erlotinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered during first-line chemotherapy; Interrupt or complete planned chemotherapy, including maintenance therapy (First-line therapy)
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Progression after first-line therapy (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

gefitinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Sensitizing EGFR mutation discovered during first-line chemotherapy; Interrupt or complete planned chemotherapy, including maintenance therapy (First-line therapy)
- Adenocarcinoma, Large cell, Non-Small Cell Lung Cancer (NOS), Squamous cell carcinoma; Progression after first-line therapy (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

erlotinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** EGFR exon 19 deletion

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Leptomeningeal metastases; Weekly pulse erlotinib (Not specified)

Reference: NCCN Guidelines® - NCCN-Central Nervous System Cancers [Version 1.2017]

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afatinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Brain metastases; Recurrent disease; Use agents active against primary tumor (Not specified)

Reference: NCCN Guidelines® - NCCN-Central Nervous System Cancers [Version 1.2017]

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afatinib + cetuximab

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

Other criteria: EGFR T790M negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Progression after EGFR TKI + chemotherapy (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

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erlotinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Brain metastases; Recurrent disease; Use agents active against primary tumor (Not specified)

Reference: NCCN Guidelines® - NCCN-Central Nervous System Cancers [Version 1.2017]

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

gefitinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Brain metastases; Recurrent disease; Use agents active against primary tumor (Not specified)

Reference: NCCN Guidelines® - NCCN-Central Nervous System Cancers [Version 1.2017]

alectinib

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

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Likewise, crizotinib, ceritinib, and alectinib are not recommended for patients with sensitizing EGFR mutations who relapse on erlotinib, gefitinib, or afatinib."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

ceritinib

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

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Likewise, crizotinib, ceritinib, and alectinib are not recommended for patients with sensitizing EGFR mutations who relapse on erlotinib, gefitinib, or afatinib."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

crizotinib

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

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Likewise, crizotinib, ceritinib, and alectinib are not recommended for patients with sensitizing EGFR mutations who relapse on erlotinib, gefitinib, or afatinib."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 8.2017]

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 Clinical Trials Information

Clinical Trials information is current as of 2017-09-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

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: EGFR mutation

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

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

Other inclusion criteria: ERBB2 negative, ER/PR status

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Location: Australia

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: EGFR mutation

Other identifier: 2014-11-078

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

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

NCT02101385
A Phase II Randomized Controlled Trial of Genomically Directed Therapy After Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer: Hoosier Oncology Group BRE12-158

Cancer type: Breast Cancer

Variant class: EGFR 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: cetuximab

Location: United States

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

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

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

Cancer type: Breast Cancer

Variant class: EGFR 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 or greater/Refractory/Relapsed, 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.

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: EGFR activating mutation

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

Phase: II

Therapies: afatinib, osimertinib

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: Fox Chase Cancer Center [888-369-2427]

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: EGFR 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 or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: erlotinib

Location: United States

US States: AZ, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, UT, WA

US Contact: Pam Mangat [pam.mangat@asco.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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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (continued)

NCT02689336
Phase II Clinical Trial Treating Relapsed/ Recurrent/Refractory Pediatric Solid Tumors With the Genomically-Targeted Agent Erlotinib in Combination With Temozolomide

Cancer type: Unspecified Solid Tumor

Variant class: EGFR mutation

Other identifiers: 201604002, NCI-2016-00549

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

Phase: II

Therapy: erlotinib + chemotherapy

Location: United States

US State: MO

US Contact: Dr. Robert Hayashi [314-454-6018; Hayashi_R@kids.wustl.edu]

NCT02442414
A Phase 1 Study of KBP-5209 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB aberration

Other identifiers: 2014-0891, 5209-CPK-1001, NCI-2015-00881

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

Phase: I/II

Therapy: pirotinib

Location: United States

US States: IN, TX, UT

US Contact: Matthew S. Hunt [608-332-8641; Matthew.hunt2@covance.com]

NCT02590952
An Open-label, Multi-Centered, Dose Escalation Phase Ib Study (Expansion Stage) of Epitinib (HMPL-813) in Patients With Advanced Solid Tumors

Cancer type: Unspecified Cancer

Variant class: EGFR exon 19 deletion

Other identifiers: 2010-813-00CH1, CTR20130972

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

Phase: I

Therapy: epitinib

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.

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EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC (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: EGFR 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 Cancer

Variant class: EGFR aberration

Other identifier: ASLAN001-002SG

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

TP53 p.(L194R) c.581T>G

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC

Population segments: Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapies: hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention

Location: Norway

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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TP53 p.(L194R) c.581T>G (continued)

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC

Population segments: Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapies: hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention

Location: Norway

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC

Population segments: Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV, Triple receptor negative

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

Phase: II

Therapy: olaparib + chemotherapy + radiation therapy + surgical intervention

Location: Norway

NCT03096054
A Cancer Research UK (CR-UK) Phase I Trial of LY3143921 a Cdc7 Inhibitor in Adult Patients With Advanced Solid Tumours

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifier: CRUKD/17/004

Population segments: HER2 negative, Line of therapy N/A, Squamous Cell, Stage III, Stage IV, Triple receptor negative

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

Phase: I

Therapy: LY3143921

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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TP53 p.(L194R) c.581T>G (continued)

NCT02432963
A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 116634, 122284, 122771, 124524, 15002, 17012, NCI-2015-00653

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

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

Phase: I

Therapy: pembrolizumab + p53MVA

Location: United States

US State: CA

US Contact: Vincent Chung [800-826-4673]

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

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

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

Phase: II

Therapy: MK-1775 + olaparib

Location: United States

US States: CT, MA, TN

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

No NCT ID - see other identifier(s)
An Open-Label Study of the Safety, Tolerability, and Pharmacokinetic/ Pharmacodynamic Profile of VX-970 as a Single Agent in Combination with Carboplatin in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: EudraCT Number: 2013-005100-34, VX13-970-002

Population segments: (N/A), Adenocarcinoma, HER2 negative, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapies: VX-970, VX-970 + chemotherapy

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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TP53 p.(L194R) c.581T>G (continued)

NCT02354547
A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

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

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

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Location: United States

US State: TX

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

EGFR amplification

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: EGFR amplification

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

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

Other inclusion criteria: ERBB2 negative, ER/PR status

Exclusion criteria variant class: ERBB2 amplification

Phase: II

Therapy: alpelisib

Location: Australia

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: EGFR amplification

Other identifier: 2014-11-078

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

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EGFR amplification (continued)

NCT02101385
A Phase II Randomized Controlled Trial of Genomically Directed Therapy After Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer: Hoosier Oncology Group BRE12-158

Cancer type: Breast Cancer

Variant class: EGFR 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: cetuximab

Location: United States

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

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

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

Cancer type: Breast Cancer

Variant class: EGFR 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 or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

NCT02447419
Study to Evaluate the Safety and Efficacy of Gefitinib, in Subjects With EFGR Amplification Refractory Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: EGFR amplification

Other identifier: 2014-10-029

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

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

Phase: II

Therapy: gefitinib

Location: Republic of Korea

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EGFR amplification (continued)

NCT02442414
A Phase 1 Study of KBP-5209 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB aberration

Other identifiers: 2014-0891, 5209-CPK-1001, NCI-2015-00881

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

Phase: I/II

Therapy: pirotinib

Location: United States

US States: IN, TX, UT

US Contact: Matthew S. Hunt [608-332-8641; Matthew.hunt2@covance.com]

No NCT ID - see other identifier(s)
Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

Cancer type: Unspecified Solid Tumor

Variant class: EGFR amplification

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 Cancer

Variant class: EGFR aberration

Other identifier: ASLAN001-002SG

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

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.

EGFR p.(E746_A750del) c.2235_2249delGGAATTAAGAGAAGC

Variant Class	Evidence Items
ERBB aberration	2
↳ EGFR aberration	6
↳ EGFR positive	0
↳ EGFR mutation status	0
↳ EGFR mutation	5
↳ EGFR exon 19 mutation	0
↳ EGFR exon 19 activating mutation	0
↳ EGFR exon 19 sensitizing mutation	0
↳ EGFR exon 19 deletion	15
↳ EGFR activating mutation	3
↳ EGFR exon 19 activating mutation	0
↳ EGFR exon 19 sensitizing mutation	0
↳ EGFR exon 19 deletion	15
↳ EGFRi sensitizing mutation	10
↳ EGFR exon 19 sensitizing mutation	0
↳ EGFR exon 19 deletion	15

TP53 p.(L194R) c.581T>G

Variant Class	Evidence Items
TP53 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.

EGFR amplification

Variant Class	Evidence Items
ERBB aberration	2
↳ EGFR aberration	6
↳ EGFR positive	0
↳ EGFR amplification	4

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Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Allele Frequency	Transcript	Variant Effect	Gene Class	Variant Class
EGFR	p.(E746_A750del)	c.2235_2249delGGAATTAAGAGAAGC	COSM6223	84.03%	NM_005228.3	nonframeshift Deletion	Gain of Function	Hotspot
TP53	p.(L194R)	c.581T>G	COSM44571	21.58%	NM_000546.5	missense	Loss of Function	Hotspot

Copy Number Variations

Gene	Locus	Copy Number
EGFR	chr7:55092604	13.03

Referring pathology dept:

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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