[Oncofocus] Patient Test Report

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ONC17			
Surname		**Requesting Clinician**	
Forename			
DOB		**Date requested**	
Gender	Male		
Histology #		**Tumour %**	45-50%
Primary site	Pancreatic	**Tumour %**	-
Tumour subtype	Mets Adenocarcinoma With Neuroendocrine Differentiation	**(macrodissected)**	
Tissue Type	Liver		

Comment:

Oncofocus targets 237 genes 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 582 anti-cancer targeted therapies.

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 for the analysis of ongogenes, fusion genes and tumour supressor genes. Unfortunatly copy number analysis failed to meet quality control criteria and therefore copy number was not analysed.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Pancreatic Cancer

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

Gene Variant			EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
BRCA2	c.6556_6557insA	p.(Ser2186fs)	○ (1)	○ (1)	✖	✖	● (4)
KRAS	c.35G>T	p.(Gly12Val)	⊘ (3)	⊘ (2)	⊘ (4)	⊘ (3)	● (16)
RET fusion			✖	✖	✖	○ (2)	● (5)

EMA: European Medicine Agency, **US-FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **US-NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence. Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value of 99%. Copy number variants of a >5% confidence value of ≥4 after normalisation are classified as amplified when the tumour% >50%. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control. With a sensitivity of 93% and PPV of 96%. 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.

DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2017.03(003).

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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

BRCA2 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
olaparib	○	✖	✖	✖	● (II)
rucaparib	✖	○	✖	✖	✖
prexasertib	✖	✖	✖	✖	● (II)
BGB-290 + BGB-A317	✖	✖	✖	✖	● (I)
talazoparib + chemotherapy	✖	✖	✖	✖	● (I)

KRAS G12 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
cetuximab	⊘	⊘	⊘	⊘	✖
cetuximab + oxaliplatin	⊘	✖	✖	✖	✖
panitumumab + oxaliplatin	⊘	✖	✖	✖	✖
panitumumab	✖	⊘	⊘	⊘	✖
cetuximab + chemotherapy	✖	✖	⊘	✖	✖
panitumumab + chemotherapy	✖	✖	⊘	✖	✖
EGFR tyrosine kinase inhibitor	✖	✖	✖	⊘	✖
MK-1775 + olaparib	✖	✖	✖	✖	● (II)
sorafenib	✖	✖	✖	✖	● (II)
sorafenib + chemotherapy	✖	✖	✖	✖	● (II)
afatinib + selumetinib	✖	✖	✖	✖	● (I/II)
BAL-3833	✖	✖	✖	✖	● (I/II)

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

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Relevant Therapy Summary (continued)

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

KRAS G12 mutation (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
dacomitinib + PD-0325901	✖	✖	✖	✖	● (I/II)
lapatinib + trametinib	✖	✖	✖	✖	● (I/II)
LNP3794	✖	✖	✖	✖	● (I/II)
palbociclib + PD-0325901	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
abemaciclib + LY3214996 , LY3214996 , LY3214996 + chemotherapy, LY3214996 + midazolam	✖	✖	✖	✖	● (I)
BGB-283	✖	✖	✖	✖	● (I)
LTT-462	✖	✖	✖	✖	● (I)
LXH254	✖	✖	✖	✖	● (I)
RO-5126766	✖	✖	✖	✖	● (I)
trametinib + radiation therapy, trametinib + surgical intervention	✖	✖	✖	✖	● (I)

RET fusion

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
vandetanib	✖	✖	✖	○	● (II)
cabozantinib	✖	✖	✖	○	✖
ponatinib	✖	✖	✖	✖	● (II)
sorafenib	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)

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

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Relevant Therapy Summary (continued)

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

RET fusion (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
sitravatinib	✖	✖	✖	✖	● (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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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 2017-01-03. For the most up-to-date information, search www.ema.europa.eu/ema.

BRCA2 mutation

○ olaparib

Cancer type: Ovarian Cancer **Label as of:** 2016-11-03 **Variant class:** BRCA mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003726/WC500180151.pdf

KRAS G12 mutation

⊘ cetuximab, cetuximab + oxaliplatin

Cancer type: Colorectal Cancer **Label as of:** 2015-02-03 **Variant class:** KRAS exon 2 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000558/WC500029119.pdf

⊘ panitumumab + oxaliplatin

Cancer type: Colorectal Cancer **Label as of:** 2016-11-16 **Variant class:** KRAS exon 2 mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000741/WC500047710.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 2017-01-03. For the most up-to-date information, search www.fda.gov.

BRCA2 mutation

○ rucaparib

Cancer type: Ovarian Cancer **Label as of:** 2016-12-19 **Variant class:** BRCA mutation

Indications and usage:

RUBRACA™ is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA™.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209115s000lbl.pdf

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KRAS G12 mutation

cetuximab

Cancer type: Colorectal Cancer **Label as of:** 2015-04-10 **Variant class:** KRAS G12 mutation

Indications and usage:

Erbitux® is an epidermal growth factor receptor (EGFR) antagonist indicated for treatment of:

Head and Neck Cancer

- Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy.
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU.
- Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy.

Colorectal Cancer

K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests

- in combination with FOLFIRI for first-line treatment,
- in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy,
- as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan.

Limitation of Use: Erbitux® is not indicated for treatment of *Ras*-mutant colorectal cancer.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125084s262lbl.pdf

panitumumab

Cancer type: Colorectal Cancer **Label as of:** 2015-03-11 **Variant class:** KRAS G12 mutation

Indications and usage:

Vectibix® is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild-type KRAS (exon 2) metastatic colorectal cancer (mCRC) as determined by an FDA-approved test for this use:

- In combination with FOLFOX for first-line treatment.
- As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Limitation of Use: Vectibix® is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125147s200lbl.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 2016-12-01. For the most up-to-date information, search www.esmo.org.

KRAS G12 mutation

⊘ cetuximab

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 2 mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic colorectal cancer (All treatment lines)

Reference: ESMO Clinical Practice Guidelines - Metastatic Colorectal Cancer [Ann Oncol (2014) 25 (suppl 3): iii1-iii9.]

⊘ cetuximab + chemotherapy

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 2 mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic colorectal cancer (All treatment lines)

Reference: ESMO Clinical Practice Guidelines - Metastatic Colorectal Cancer [Ann Oncol (2014) 25 (suppl 3): iii1-iii9.]

⊘ panitumumab

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 2 mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic colorectal cancer (All treatment lines)

Reference: ESMO Clinical Practice Guidelines - Metastatic Colorectal Cancer [Ann Oncol (2014) 25 (suppl 3): iii1-iii9.]

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KRAS G12 mutation (continued)

⊘ panitumumab + chemotherapy

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 2 mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic colorectal cancer (All treatment lines)

Reference: ESMO Clinical Practice Guidelines - Metastatic Colorectal Cancer [Ann Oncol (2014) 25 (suppl 3): iii1-iii9.]

⊘ cetuximab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic disease (Not specified)

Reference: ESMO Clinical Practice Guidelines - Rectal Cancer [Ann Oncol 2013; 24 (Suppl 6): vi81-vi88.]

⊘ panitumumab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

ESMO Recommendation category: II, A

Population segment (Line of therapy):
- Metastatic disease (Not specified)

Reference: ESMO Clinical Practice Guidelines - Rectal Cancer [Ann Oncol 2013; 24 (Suppl 6): vi81-vi88.]

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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 2016-12-01. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

KRAS G12 mutation

⊘ cetuximab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic colorectal cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 1.2017]

⊘ cetuximab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic colorectal cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Rectal Cancer [Version 1.2017]

⊘ panitumumab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic colorectal cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 1.2017]

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KRAS G12 mutation (continued)

⊘ panitumumab

Cancer type: Colorectal Cancer **Variant class:** KRAS mutation

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic colorectal cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Rectal Cancer [Version 1.2017]

⊘ EGFR tyrosine kinase inhibitor

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

Summary:

NCCN Guidelines® do not contain a recommendation regarding KRAS mutations and tyrosine kinase inhibitor (TKI) therapy in non-small cell lung cancer, but include the following evidentiary statements:

- "KRAS mutations are associated with intrinsic EGFR TKI resistance, and KRAS gene sequencing could be useful for the selection of patients as candidates for EGFR TKI therapy. KRAS testing may identify patients who may not benefit from further molecular diagnostic testing."
- "KRAS mutations are also predictive of lack of benefit from platinum/vinorelbine chemotherapy or EGFR TKI therapy."
- "Sensitizing TKI therapy is not effective in patients with KRAS mutations, ALK gene rearrangements, or ROS1 rearrangements."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 3.2017]

RET fusion

○ cabozantinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** RET fusion

US-NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 3.2017]

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RET fusion (continued)

vandetanib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** RET fusion

US-NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 3.2017]

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-12-01. 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'.

BRCA2 mutation

NCT02677038
Olaparib for BRCAness Phenotype in Pancreatic Cancer: Phase II Study

Cancer type: Pancreatic Cancer

Variant class: BRCA mutation

Other identifiers: 2015-0503, NCI-2016-00351, TrialTroveID-272870

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

Phase: II

Therapy: olaparib

Location: United States

US State: TX

US Contact: Dr. Milind Javle [713-792-2828]

NCT02677038
Olaparib for BRCAness Phenotype in Pancreatic Cancer: Phase II Study

Cancer type: Pancreatic Cancer

Variant class: FANC mutation

Other identifiers: 2015-0503, NCI-2016-00351, TrialTroveID-272870

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

Phase: II

Therapy: olaparib

Location: United States

US State: TX

US Contact: Dr. Milind Javle [713-792-2828]

NCT02660034
A Phase 1b, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics and Antitumor Activity of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Combination With the PARP Inhibitor BGB-290 in Subjects With Advanced Solid Tumors

Cancer type: Pancreatic Cancer

Variant class: HRR pathway

Other identifiers: BGB-A317/BGB-290_Study_001, TrialTroveID-271778

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

Phase: I

Therapy: BGB-290 + BGB-A317

Location: Australia

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BRCA2 mutation (continued)

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: Pro00014171, TAPUR, TrialTroveID-273941

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: olaparib

Location: United States

US States: IL, MI, NC, PA, SD

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

NCT02873975
A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: 16-281, TrialTroveID-284902

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

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shapiro@dfci.harvard.edu]

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 Cancer

Variant class: DNA repair pathway

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

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

Phase: II

Therapy: olaparib

Location: United States

US States: CT, MA

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

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BRCA2 mutation (continued)

NCT02873975
A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: HRR pathway

Other identifiers: 16-281, TrialTroveID-284902

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

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shapiro@dfci.harvard.edu]

NCT02317874
A Phase I Study of BMN 673 in Combination with Carboplatin and Paclitaxel in Patients with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: 051513, 9782, NCI 9782, NCI-2014-02474, NCI9782, TrialTroveID-248774

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

Phase: I

Therapy: talazoparib + chemotherapy

Location: United States

US States: NJ, WI

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

KRAS G12 mutation

NCT02450656
Phase I/II study with the combination of afatinib and selumetinib in advanced KRAS mutant positive and PIK3CA wildtype colorectal, non-small cell lung and pancreatic cancer

Cancer type: Pancreatic Cancer

Variant class: KRAS exon 2 mutation

Other identifiers: EudraCT Number: 2014-001855-22, M14AFS, NL49983.031.14, TrialTroveID-251759

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

Other inclusion criteria: PIK3CA wild type

Phase: I/II

Therapy: afatinib + selumetinib

Location: Netherlands

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KRAS G12 mutation (continued)

NCT02039336
Phase I/II Study With the Combination of Dacomitinib and PD-0325901 in Metastatic KRAS Mutation Positive Colorectal, Non-small Cell Lung and Pancreatic Cancer

Cancer type: Pancreatic Cancer

Variant class: KRAS exon 2 mutation

Other identifiers: EudraCT Number: 2013-003299-10, M13DAP, NL45985.031.13, TrialTroveID-200856

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

Phase: I/II

Therapy: dacomitinib + PD-0325901

Location: Netherlands

NCT02230553
Phase I/II study with lapatinib plus trametinib in patients with metastatic KRAS mutant colorectal, non-small cell lung and pancreatic cancer

Cancer type: Pancreatic Cancer

Variant class: KRAS exon 2 mutation

Other identifiers: EudraCT Number: 2014-002209-39, M14LTK, NL49551.031.14, TrialTroveID-214278

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

Other inclusion criteria: PIK3CA wild type

Phase: I/II

Therapy: lapatinib + trametinib

Location: Netherlands

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

Cancer type: Pancreatic Cancer

Variant class: RAS/RAF/MEK/ERK pathway

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

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

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

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KRAS G12 mutation (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: KRAS mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

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

Phase: II

Therapy: MK-1775 + olaparib

Location: United States

US States: CT, MA

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

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: KRAS 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

Therapy: sorafenib

Location: France

NCT02747537
Phase II Clinical Trial Treating Relapsed/Recurrent/Refractory Pediatric Solid Tumors With the Genomically-Targeted Agent Sorafenib in Combination With Irinotecan

Cancer type: Unspecified Solid Tumor

Variant class: RAS mutation

Other identifiers: 201605006, NCI-2016-00680, TrialTroveID-277232

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

Phase: II

Therapy: sorafenib + chemotherapy

Location: United States

US State: MO

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

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KRAS G12 mutation (continued)

NCT02022982
Phase I/II Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the MEK Inhibitor PD-0325901 for Patients with KRAS Mutant Non-Small Cell Lung Cancer and Other Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: KRAS mutation

Other identifiers: 13-506, NCI-2014-00940, TrialTroveID-200043

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

Phase: I/II

Therapy: palbociclib + PD-0325901

Location: United States

US State: MA

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

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: RAS mutation

Other identifiers: 4232, PanRAF, TrialTroveID-257046

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

Phase: I/II

Therapy: BAL-3833

Location: United Kingdom

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: RAS mutation

Other identifier: TrialTroveID-250171

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

Phase: I/II

Therapy: LNP3794

Location: United Kingdom

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KRAS G12 mutation (continued)

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: KRAS mutation

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

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

Phase: I

Therapy: RO-5126766

Location: United Kingdom

NCT02015117
A Phase I Study of Trametinib in Combination With Radiation Therapy for Brain Metastases

Cancer type: Unspecified Cancer

Variant class: KRAS mutation

Other identifiers: 2013C0115, 9458, NCI-2013-02343, OSU 13197, OSU-13197, TrialTroveID-199440

Population segments: Adjuvant, CNS mets, Stage IV

Phase: I

Therapies: trametinib + radiation therapy, trametinib + surgical intervention

Location: United States

US States: IL, OH

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

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

Cancer type: Unspecified Cancer

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: 16419, EudraCT Number: 2016-001907-21, I8S-MC-JUAB, TrialTroveID-280743

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

Phase: I

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

Location: United States

US State: TN

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

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KRAS G12 mutation (continued)

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: RAS/RAF/MEK/ERK pathway

Other identifier: TrialTroveID-261285

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

Phase: I

Therapy: BGB-283

Locations: Australia, New Zealand

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

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: CLTT462X2101, EudraCT number: 2015-003614-24, NCI-2016-00539, TrialTroveID-275107

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

Phase: I

Therapy: LTT-462

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

US States: NY, TX

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

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

Cancer type: Unspecified Solid Tumor

Variant class: RAS/RAF/MEK/ERK pathway

Other identifiers: 2015-0913, CLXH254X2101, EudraCT Number: 2015-003421-33, NCI-2015-02280, REec-2016-2132, TrialTroveID-268216

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

Phase: I

Therapy: LXH254

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

US States: NY, 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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RET fusion

NCT02013089
A Pilot Study of Genomic Sequencing Guided Individualized Therapy in Gastrointestinal Cancers

Cancer type: Pancreatic Cancer

Variant class: RET fusion

Other identifiers: GIHSYSU04, GITIC, TrialTroveID-231676

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

Phase: II

Therapy: vandetanib

Location: China

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

Cancer type: Pancreatic Cancer

Variant class: RET aberration

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

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

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: RET fusion

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

Therapy: sorafenib

Location: France

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

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RET fusion (continued)

NCT02272998
Phase II Study Of Ponatinib For Advanced Cancers With Genomic Alterations In Fibroblastic Growth Factor Receptor (FGFR) And Other Genomic Targets (KIT, Pdgfra, RET FLT3, ABL1)

Cancer type: Unspecified Solid Tumor

Variant class: RET aberration

Other identifiers: 14078, 2014C0143, NCI-2014-01499, OSU-14078, TrialTroveID-219466

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

Phase: II

Therapy: ponatinib

Location: United States

US States: MI, OH

US Contact: The Ohio State University Comprehensive Cancer Center [800-293-5066]

NCT02219711
A Phase I/Ib Study of MGCD516 in Patients With Advanced Solid Tumor Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: RET fusion

Other identifiers: 516-001, 76853, AAAO0006, NCI-2014-01866, TrialTroveID-197300

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

Phase: I

Therapy: sitravatinib

Location: United States

US States: AL, CA, MA, MI, MO, NM, NY, SC, TN, TX, UT, WA, WI

US Contact: Mirati Therapeutics Study Locator Services [844-356-0895; miratistudylocator@emergingmed.com]

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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.

BRCA2 mutation

Variant Class	Evidence Items
DNA repair pathway	1
↳ BRCA mutation	3
↳ BRCA2 mutation	3
HRR pathway	2
↳ BRCA mutation	3
↳ BRCA2 mutation	3
Fanconi anemia pathway	0
↳ FANC mutation	1
↳ BRCA2 mutation	3
↳ BRCA mutation	3
↳ BRCA2 mutation	3

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Appendix: 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.

KRAS G12 mutation

Variant Class	Evidence Items
RAS/RAF/MEK/ERK pathway	5
↳ RAS mutation	3
↳ RAS activating mutation	0
↳ KRAS activating mutation	0
↳ KRAS G12 mutation	2
↳ KRAS mutation	12
↳ KRAS activating mutation	0
↳ KRAS G12 mutation	2
↳ KRAS exon 2 mutation	9
↳ KRAS G12 mutation	2

RET fusion

Variant Class	Evidence Items
RET aberration	2
↳ RET fusion	5

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

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

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:
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(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

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