[Oncofocus] Patient Test Report

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ONC17			
Surname		**Requesting Clinician**	
Forename		**Contact details**	
DOB		**Date requested**	
Gender	Male		
Histology #		**Tumour %**	-
Primary site	Colon	**Tumour %**	80%
Tumour subtype	Mucinous Adenocarcinoma	**(macrodissected)**	
Tissue Type	Colon		

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 635 anti-cancer targeted therapies.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Colorectal 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
KRAS	c.436G>A	p.(Ala146Thr)	25%	⊘ (3)	⊘ (2)	⊘ (4)	⊘ (3)	● (35)
MSH2	c.387_388delTC	p.(Gln130fs)	24%	✖	✖	✖	● (2)	● (3)
FGFR2	c.755C>T	p.(Ser252Leu)	52%	✖	✖	✖	✖	● (8)
FBXW7	c.1099C>T	p.(Arg367Ter)	20%	✖	✖	✖	✖	● (2)
PIK3CA	c.3140A>G	p.(His1047Arg)	16%	✖	✖	✖	✖	● (14)
TP53	c.216delC	p.(Val73fs)	30%	✖	✖	✖	✖	● (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(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.

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

KRAS A146 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	✖	✖	✖	⊘	✖
bevacizumab + chemotherapy	✖	✖	✖	✖	● (III)
AKT inhibitor + MEK inhibitor	✖	✖	✖	✖	● (II/III)
aflibercept + chemotherapy	✖	✖	✖	✖	● (II)
MK-1775 + olaparib	✖	✖	✖	✖	● (II)
palbociclib	✖	✖	✖	✖	● (II)
regorafenib	✖	✖	✖	✖	● (II)
regorafenib, vorinostat + hydroxychloroquine	✖	✖	✖	✖	● (II)
sorafenib	✖	✖	✖	✖	● (II)
sorafenib + chemotherapy	✖	✖	✖	✖	● (II)
cetuximab + Hu5F9-G4	✖	✖	✖	✖	● (I/II)
dacomitinib + PD-0325901	✖	✖	✖	✖	● (I/II)
lapatinib + trametinib	✖	✖	✖	✖	● (I/II)
LNP3794	✖	✖	✖	✖	● (I/II)
MCLA-128	✖	✖	✖	✖	● (I/II)
navitoclax + trametinib	✖	✖	✖	✖	● (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 A146 mutation (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
palbociclib + PD-0325901	✖	✖	✖	✖	● (I/II)
ribociclib + trametinib	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
abemaciclib + LY3214996 , LY3214996 , LY3214996 + chemotherapy, LY3214996 + midazolam	✖	✖	✖	✖	● (I)
BAL-3833	✖	✖	✖	✖	● (I)
BGB-283	✖	✖	✖	✖	● (I)
binimetinib + chemotherapy	✖	✖	✖	✖	● (I)
CB-5083	✖	✖	✖	✖	● (I)
LTT-462	✖	✖	✖	✖	● (I)
LXH254	✖	✖	✖	✖	● (I)
LY2228820 + prexasertib	✖	✖	✖	✖	● (I)
MGD007	✖	✖	✖	✖	● (I)
MK-1775 + chemotherapy	✖	✖	✖	✖	● (I)
MM-151 + trametinib	✖	✖	✖	✖	● (I)
pembrolizumab + SCH-900353, ridaforolimus + SCH-900353, SCH-900353 + chemotherapy	✖	✖	✖	✖	● (I)
RO-5126766	✖	✖	✖	✖	● (I)
selinexor	✖	✖	✖	✖	● (I)
selumetinib + ciclosporin	✖	✖	✖	✖	● (I)
sEphB4-HSA	✖	✖	✖	✖	● (I)
trametinib + radiation therapy, trametinib + surgical intervention	✖	✖	✖	✖	● (I)

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Relevant Therapy Summary (continued)

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MSH2 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
nivolumab	✖	✖	✖	●	✖
pembrolizumab	✖	✖	✖	●	✖
BMS-986016 + nivolumab, cobimetinib + ipilimumab + nivolumab, daratumumab + nivolumab, ipilimumab + nivolumab, nivolumab	✖	✖	✖	✖	● (II)
olaparib	✖	✖	✖	✖	● (II)
BGB-290 + BGB-A317	✖	✖	✖	✖	● (I)

FGFR2 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
AZD4547	✖	✖	✖	✖	● (II)
infigratinib	✖	✖	✖	✖	● (II)
pazopanib	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
TAS-120	✖	✖	✖	✖	● (I/II)
FF-284	✖	✖	✖	✖	● (I)
HMPL-453	✖	✖	✖	✖	● (I)
PRN-1371	✖	✖	✖	✖	● (I)

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Relevant Therapy Summary (continued)

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FBXW7 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
palbociclib	✖	✖	✖	✖	● (II)
prexasertib	✖	✖	✖	✖	● (II)

PIK3CA H1047R mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
MEK inhibitor + PIK3/mTOR inhibitor, PIK3/mTOR inhibitor	✖	✖	✖	✖	● (II/III)
AZD-5363 + olaparib	✖	✖	✖	✖	● (II)
everolimus	✖	✖	✖	✖	● (II)
sirolimus	✖	✖	✖	✖	● (II)
CB-839 + chemotherapy	✖	✖	✖	✖	● (I/II)
MCLA-128	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
ARQ-751	✖	✖	✖	✖	● (I)
ASN-003	✖	✖	✖	✖	● (I)
AZD-5363	✖	✖	✖	✖	● (I)
GDC-0077	✖	✖	✖	✖	● (I)
MSC-2363318A	✖	✖	✖	✖	● (I)
palbociclib + pictilisib, palbociclib + taselisib	✖	✖	✖	✖	● (I)
PQR-309	✖	✖	✖	✖	● (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

TP53 mutation

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

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

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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 2017-04-03. For the most up-to-date information, search www.ema.europa.eu/ema.

KRAS A146 mutation

⊘ cetuximab, cetuximab + oxaliplatin

Cancer type: Colorectal Cancer **Label as of:** 2015-02-03 **Variant class:** KRAS exon 4 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:** 2017-03-09 **Variant class:** KRAS exon 4 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 2017-04-03. For the most up-to-date information, search www.fda.gov.

KRAS A146 mutation

⊘ cetuximab

Cancer type: Colorectal Cancer **Label as of:** 2016-10-11 **Variant class:** KRAS A146 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:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125084s265lbl.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.

KRAS A146 mutation (continued)

panitumumab

Cancer type: Colorectal Cancer **Label as of:** 2015-03-11 **Variant class:** KRAS A146 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 2017-03-20. For the most up-to-date information, search www.esmo.org.

KRAS A146 mutation

⊘ cetuximab

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 4 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 4 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 4 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 A146 mutation (continued)

panitumumab + chemotherapy

Cancer type: Colorectal Cancer **Variant class:** KRAS exon 4 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 2017-03-20. 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 A146 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 2.2017]

⊘ 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 3.2017]

⊘ 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 2.2017]

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KRAS A146 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 3.2017]

EGFR tyrosine kinase inhibitor

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

Summary:

NCCN Guidelines® do not contain a recommendation but include the following evidentiary statement(s):
- "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."
- "Primary resistance to EGFR TKI therapy is associated with KRAS mutation. Acquired resistance is associated with second-site mutations within the EGFR kinase domain (such as T790M), amplification of alternative kinases (such as MET), histologic transformation from NSCLC to SCLC, and epithelial to mesenchymal transition (EMT)."
- "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 5.2017]

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MSH2 mutation

nivolumab

Cancer type: Colorectal Cancer **Variant class:** MMR pathway

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Unresectable Metachronous Metastases; Previous adjuvant FOLFOX/CAPEOX within the past 12 months (Primary treatment)
- Advanced or Metastatic Disease; Not appropriate for intensive therapy (Initial therapy)
- Advanced or metastatic disease; Progression after initial therapy; If neither nivolumab or pembrolizumab previously given (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 2.2017]

nivolumab

Cancer type: Colorectal Cancer **Variant class:** MMR pathway

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Unresectable Metachronous Metastases; Previous adjuvant FOLFOX/CAPEOX within the past 12 months (Primary treatment)
- Advanced or Metastatic Disease; Not appropriate for intensive therapy (Initial therapy)
- Advanced or metastatic disease; Progression after initial therapy; If neither nivolumab or pembrolizumab previously given (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Rectal Cancer [Version 3.2017]

pembrolizumab

Cancer type: Colorectal Cancer **Variant class:** MMR pathway

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Unresectable Metachronous Metastases; Previous adjuvant FOLFOX/CAPEOX within the past 12 months (Primary treatment)
- Advanced or Metastatic Disease; Not appropriate for intensive therapy (Initial therapy)
- Advanced or metastatic disease; Progression after initial therapy; If neither nivolumab or pembrolizumab previously given (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Colon Cancer [Version 2.2017]

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MSH2 mutation (continued)

pembrolizumab

Cancer type: Colorectal Cancer **Variant class:** MMR pathway

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Unresectable Metachronous Metastases; Previous adjuvant FOLFOX/CAPEOX within the past 12 months (Primary treatment)
- Advanced or Metastatic Disease; Not appropriate for intensive therapy (Initial therapy)
- Advanced or metastatic disease; Progression after initial therapy; If neither nivolumab or pembrolizumab previously given (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Rectal Cancer [Version 3.2017]

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2017-03-01. 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'.

KRAS A146 mutation + TP53 mutation

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 classes: KRAS & 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

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

KRAS A146 mutation

NCT02885753
Systemic Oxaliplatin or Intra-arterial Chemotherapy Combined With LV5FU2 and an Target Therapy in First Line Treatment of Metastatic Colorectal Cancer Restricted to the Liver

Cancer type: Colorectal Cancer

Variant class: KRAS exon 4 mutation

Other identifiers: FFCD 1501, OSCAR, PRODIGE 49

Population segments: First line, Liver mets, Stage IV

Phase: III

Therapy: bevacizumab + chemotherapy

Location: France

NCT02162563
Treatment Strategies in Colorectal Cancer Patients With Initially Unresectable Liver-only Metastases CAIRO5 a Randomized Phase III Study of the Dutch Colorectal Cancer Group (DCCG)

Cancer type: Colorectal Cancer

Variant class: RAS mutation

Other identifiers: CAIRO 5, CAIRO5, DCCG 14-01, EudraCT Number: 2013-005435-24, NL47650.018.14

Population segments: Liver mets, Neoadjuvant, Stage IV

Phase: III

Therapy: bevacizumab + chemotherapy

Location: Netherlands

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.

KRAS A146 mutation (continued)

No NCT ID - see other identifier(s)
Molecular selection of therapy in metastatic colorectal cancer: a molecularly stratified randomised controlled trial programme

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 14893, CR13, CRUK/11/054, EudraCT Number: 2012-005111-12, FOCUS-4, FOCUS4, IRAS ID 119459, ISRCTN90061546, MREC N° 13/SC/0111, UKCRN ID: 14893

Population segments: First line, Stage III, Stage IV

Phase: II/III

Therapy: AKT inhibitor + MEK inhibitor

Location: United Kingdom

NCT02173990
A Phase 2 Study of Aflibercept and Chemotherapy as First Line Treatment for Metastatic Colorectal Cancer Assessable With DCE-US.

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: EudraCT number: 2013-004540-33, PULSAR, PULSAR-1303, RECF2410

Population segments: First line, Stage IV

Phase: II

Therapy: aflibercept + chemotherapy

Location: France

No NCT ID - see other identifier(s)
A phase II randomized study evaluating the activity and tolerability of first line treatment with bevacizumab + XELOX 2 than FOLFOX 4 + bevacizumab in patients with advanced colorectal cancer with known K-ras mutated tumor

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 2802, EudraCT Number: 2010-022091-31, GOIM 2802

Population segments: First line, Stage III, Stage IV

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Italy

No NCT ID - see other identifier(s)
Phase II study of combination chemotherapy with TS-1/irinotecan and bevacizumab as second-line therapy in patient with K-RAS mutation-type metastatic colorectal cancer

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: SRIM study, UMIN000005900

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

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Japan

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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KRAS A146 mutation (continued)

No NCT ID - see other identifier(s)
Non-resectable colorectal liver metastases of KRAS mutant type treated with oxaliplatin, fluorouracil and L-leucovorin plus bevacizumab induction toward liver R0 resection trial

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: NEXTO-mt, UMIN000009530

Population segments: Adjuvant, Liver mets, Neoadjuvant, Stage IV

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
A Phase II trial of irinotecan/ S-1 (IRIS) + alfa (panitumumab/ bevacizumab) as second line chemotherapy for metastatic colorectal cancer (mCRC).

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: IRIS-PB trial -Part B-, IRIS-PB trial -Part P-, UMIN000009317, UMIN000009318

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

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Japan

NCT01802645
Open, Randomized, Multicenter Phase II Trial With Cetuximab /5-FU/FA/ Irinotecan or Cetuximab/5-FU/FA / Irinotecan/Oxaliplatin in K-ras/B-raf Wild Type Patients or With Irinotecan/ Oxaliplatin/5-FU/FA With or Without Bevacizumab in K-ras Mutant Patients as Neoadjuvant Treatment in Patients With Non- Resectable Colorectal Liver Metastases.

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: CELIM 2- study, CELIM2, DRKS00010758, EudraCT Number: 2011-003288-31, TUD-CELIM2-050

Population segments: Adjuvant, Liver mets, Neoadjuvant, Stage IV

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Germany

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.

KRAS A146 mutation (continued)

NCT01858649
Randomized Phase II Study Comparing Pathological Responses Observed on Colorectal Cancer Metastases Resected After Preoperative Treatment Combining Bevacizumab With FOLFOX or FOLFIRI

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: BEV-ONCO2012, CTBE2013000207, EudraCT Number: 2012-005376-34

Population segments: Neoadjuvant, Stage IV

Phase: II

Therapy: bevacizumab + chemotherapy

Location: Belgium

NCT01037790
Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: NCI-2009-01467, Study 1006, UPCC 03909, UPCC03909

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

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

US Contact: Peter O'Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

NCT02316340
Modulation of Autophagy: A Clinical Study of Vorinostat Plus Hydroxychloroquine Versus Regorafenib in Refractory Metastatic Colorectal Cancer (mCRC) Patients

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: CTMS 14-2015, CTMS# 14-2015, HSC20150178H, NCI-2015-00175, NCI-2015-00203

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

Phase: II

Therapies: regorafenib, vorinostat + hydroxychloroquine

Location: United States

US State: TX

US Contact: Epp Goodwin [210-450-5798; CTRCReferral@uthscsa.edu]

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

KRAS A146 mutation (continued)

NCT02619435
Regorafenib Monotherapy as Second-line Treatment of Patients With RAS-mutant Advanced Colorectal Cancer: a Multicentre, Single-arm, Two-stage, Phase II Study

Cancer type: Colorectal Cancer

Variant class: RAS mutation

Other identifiers: EudraCT Number: 2015-001105-13, STREAM

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

Phase: II

Therapy: regorafenib

Location: Italy

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: Colorectal Cancer

Variant class: KRAS exon 4 mutation

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

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: Colorectal Cancer

Variant class: KRAS exon 4 mutation

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

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

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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KRAS A146 mutation (continued)

NCT02953782
A Phase 1b/2 Trial of Hu5F9-G4 in Combination With Cetuximab in Patients With Solid Tumors and Advanced Colorectal Cancer

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifier: 5F9004

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

Phase: I/II

Therapy: cetuximab + Hu5F9-G4

Location: United States

US States: MI, TX

US Contact: Multiple Contacts [650-352-4150; medical@fortyseveninc.com]

NCT02703571
A Phase I/II Study of Safety and Efficacy of Ribociclib (LEE011) in Combination With Trametinib (TMT212) in Patients With Metastatic or Advanced Solid Tumors

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: CTMT212X2106, EudraCT Number: 2015-005019-34, TMT212X2106

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

Phase: I/II

Therapy: ribociclib + trametinib

Locations: Australia, Belgium, Netherlands, United States

US States: AR, CA, CT, FL, TX

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

NCT02912949
A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients With Solid Tumors

Cancer type: Colorectal Cancer

Variant class: KRAS mutation status

Other identifiers: EudraCT Number: 2014-003277-42, MCLA-128-CL01, NL51045.031.14

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

Phase: I/II

Therapy: MCLA-128

Locations: Netherlands, Spain

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.

KRAS A146 mutation (continued)

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

Cancer type: Colorectal Cancer

Variant class: RAS/RAF/MEK/ERK pathway

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

NCT02906059
A Phase Ib Study Combining Irinotecan With AZD1775, a Selective Wee 1 Inhibitor, in RAS (KRAS or NRAS) or BRAF Mutated Metastatic Colorectal Cancer Patients Who Have Progressed on First Line Therapy

Cancer type: Colorectal Cancer

Variant class: KRAS A146 mutation

Other identifiers: NCI-2016-01443, S14-01168

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

Phase: I

Therapy: MK-1775 + chemotherapy

Location: United States

US State: NY

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

NCT02243917
A Phase I, Open-Label, Dose Escalation and Dose Expansion Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Effects of Orally Administered CB-5083 in Subjects With Advanced Solid Tumors

Cancer type: Colorectal Cancer

Variant class: KRAS exon 4 mutation

Other identifiers: 149511, CLC-101

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

Phase: I

Therapy: CB-5083

Location: United States

US States: AZ, CA, CO, GA, PA

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.

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KRAS A146 mutation (continued)

NCT02538627
A Phase 1 Study Evaluating the Safety, Pharmacology and Preliminary Activity of the Co-Administration of MM-151 and MM-121 in Heregulin Positive Cancer Patients

Cancer type: Colorectal Cancer

Variant class: KRAS activating mutation

Other identifiers: MM-151-01-01-02, NCI-2015-01527, VICCPHI1598

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

Other inclusion criteria: NRG1 negative

Phase: I

Therapy: MM-151 + trametinib

Location: United States

US States: CO, GA, IL, TN

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

NCT02860780
A Phase I Dose-Escalation Study of LY2606368 in Combination With Ralimetinib in Patients With Advanced or Metastatic Cancer

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 16379, EudraCT Number: 2015-005611-33, I4D-MC-JTJL

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

Phase: I

Therapy: LY2228820 + prexasertib

Locations: Germany, United States

US States: NC, TN

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

NCT02248805
A Phase I, First-in-Human, Open Label, Dose Escalation Study of MGD007, A Humanized gpA33 x CD3 Dual-Affinity Re-Targeting (DART) Protein in Patients With Relapsed/Refractory Metastatic Colorectal Carcinoma.

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 00056149, 14-524, AAAP4552, CP-MGD007-01, J14126, NCI-2015-00188

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

Phase: I

Therapy: MGD007

Location: United States

US States: FL, MA, MD, NC, OR

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.

KRAS A146 mutation (continued)

No NCT ID - see other identifier(s)
A Phase I Study to Evaluate the Safety, Tolerability and Efficacy of MK-8353 Combination Therapies in Subjects With Advanced Solid Tumors

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: EudraCT Number: 2012-002695-13, MK8353-010, NL41947.031.12

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

Phase: I

Therapies: pembrolizumab + SCH-900353, ridaforolimus + SCH-900353, SCH-900353 + chemotherapy

Location: Netherlands

NCT02078349
An Investigator Sponsored Phase I Study of the Safety, Pharmacokinetics and Pharmacodynamics of Escalating Doses Followed by Dose Expansion of the Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330) in Asian Patients With Advanced or Metastatic Solid Tumor Malignancies

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 2013/01034, KPT330-A1

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), KRAS, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: selinexor

Location: Singapore

NCT01642342
A First-In-Human Phase I Study of sEphB4-HSA in Patients With Advanced Solid Tumors With Expansion at the Maximum Tolerated Dose (MTD) or Recommended Phase II Dose (RP2D).

Cancer type: Colorectal Cancer

Variant class: KRAS mutation

Other identifiers: 0C-11-3, NCI-2012-00971

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

Phase: I

Therapy: sEphB4-HSA

Location: United States

US State: CA

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.

KRAS A146 mutation (continued)

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

Cancer type: Colorectal Cancer

Variant class: RAS mutation

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

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

Phase: I

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

Locations: Australia, United States

US States: MA, TN

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

NCT02613650
A Phase 1b Trial of a Combination of mFOLFIRI With MEK162 in Patients With Advanced KRAS Positive Metastatic Colorectal Cancers

Cancer type: Colorectal Cancer

Variant class: KRAS positive

Other identifiers: CMEK162AUS12T, HCI87144, MEK162/FOLFIRI, NCI-2016-00331

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

Phase: I

Therapy: binimetinib + chemotherapy

Location: United States

US State: UT

US Contact: Adam Blair [801-213-5759; adam.blair@hci.utah.edu]

NCT02188264
A Phase IB Study of the Combination of AZD6244 Hydrogen Sulfate (Selumetinib) and Cyclosporin A (CsA) in Patients With Advanced Solid Tumors With an Expansion Cohort in Metastatic Colorectal Cancer

Cancer type: Colorectal Cancer

Variant class: RAS mutation status

Other identifiers: 051406, 13-2628, 201409113, 9571, NCI # 9571/COMIRB # 13-2628, NCI-2014-01484, NCI-9571-CIRB, NCI/CTEP #9571, NCI9571, P9571_A01PAMDREVW01

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

Exclusion criteria variant class: BRAF mutation

Phase: I

Therapy: selumetinib + ciclosporin

Location: United States

US States: CO, MO, NC, NJ, OH, PA, 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.

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KRAS A146 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: KRAS mutation

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

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

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]

NCT02079740
An Open Label, Two-Part, Phase Ib/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of the MEK Inhibitor Trametinib and the BCL2-Family Inhibitor Navitoclax (ABT-263) in Combination in Subjects With KRAS or NRAS Mutation-Positive Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: KRAS A146 mutation

Other identifiers: 13-505, 9525, NCI-2014-00461

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

Phase: I/II

Therapy: navitoclax + trametinib

Location: United States

US State: MA

US Contact: Cancer Trials Call Center [877-789-6100]

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.

KRAS A146 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

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.

No identifiers available
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

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

Phase: I/II

Therapy: LNP3794

Location: United Kingdom

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

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

Phase: I

Therapy: RO-5126766

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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KRAS A146 mutation (continued)

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

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.

NCT02437227
A Phase I, 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

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

Phase: I

Therapy: BAL-3833

Location: United Kingdom

No identifiers available
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

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

Phase: I

Therapy: BGB-283

Locations: 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.

KRAS A146 mutation (continued)

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

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

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.

MSH2 mutation

NCT02060188
A Phase 2 Clinical Trial of Nivolumab, or Nivolumab Combinations in Recurrent and Metastatic Microsatellite High (MSI-H) and Non-MSI-H Colon Cancer

Cancer type: Colorectal Cancer

Variant class: DNA repair pathway

Other identifiers: 00052582, 00052582, 14-166, 2013-1015, CA 209 142, CA209-142, CheckMate 142, EudraCT Number: 2013-003939-30, ICORG 14-19, NCI-2014-00793, REec-2014-0832, RWF_CA209-142, VICCGI13104

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

Phase: II

Therapies: BMS-986016 + nivolumab, cobimetinib + ipilimumab + nivolumab, daratumumab + nivolumab, ipilimumab + nivolumab, nivolumab

Locations: Australia, Belgium, Canada, France, Ireland, Italy, Spain, United States

US States: AZ, CA, GA, MA, MN, NC, OR, PA, TN, TX

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

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: Colorectal Cancer

Variant class: MMR pathway

Other identifier: BGB-A317/BGB-290_Study_001

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

Phase: I

Therapy: BGB-290 + BGB-A317

Location: Australia

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, 16-314, NCI-2016-00922, OLAPCO

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.

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.

FGFR2 mutation

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

Cancer type: Colorectal Cancer

Variant class: FGFR aberration

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

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: FGFR2 mutation

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH

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

Therapy: AZD4547

Location: United States

US States: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

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

NCT02450136
A Phase II Study Evaluate the Safety and Efficacy of Pazopanib, in Subjects With FGFR2 Amplification, FGFR2 Mutation Refractory Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: FGFR2 mutation

Other identifier: 2015-01-135

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

Phase: II

Therapy: pazopanib

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.

FGFR2 mutation (continued)

NCT02160041
Modular Phase II Study to Link Targeted Therapy to Patients With Pathway Activated Tumors: Module 6 - BGJ398 for Patients With Tumors With FGFR Genetic Alterations

Cancer type: Unspecified Solid Tumor

Variant class: FGFR aberration

Other identifiers: 00058827, 15.0136(UofL), 2014-0569, CBGJ398XUS04, "CBGJ398XUS04, Signature", CTMS# 14-2025, F15083

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

Phase: II

Therapy: infigratinib

Location: United States

US States: IN, NC, NM, OR, WA

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

NCT02052778
A Dose-Finding Phase I Study of TAS-120 in Patients With Advanced Solid Tumors with or without Fibroblast Growth Factor/Receptor (FGF/FGFR)-Related Abnormalities Followed By a Phase II Study in Patients with Advanced Solid Tumors or Multiple Myeloma with FGF/FGFR-Related Abnormalities

Cancer type: Unspecified Solid Tumor

Variant class: FGFR mutation

Other identifiers: 14-135, 2014-0069, EudraCT Number: 2013-004810-16, TPU-TAS-120-101

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

Phase: I/II

Therapy: TAS-120

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

US States: MA, TX

US Contact: Dr. Robert Winkler [855-598-8259; rwinkler@taihooncology.com]

NCT01948297
A Phase I, Gene Alteration-based, Open Label, Multicenter Study of Oral Debio 1347 (CH5183284) in Patients With Advanced Solid Malignancies, Whose Tumours Have an Alteration of the FGFR 1, 2 or 3 Genes

Cancer type: Unspecified Solid Tumor

Variant class: FGFR2 aberration

Other identifiers: 13-131, 13-251, 2014-1045, Debio 1347-101, EudraCT Number: 2013-000316-19, NCI-2014-00203

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

Phase: I

Therapy: FF-284

Locations: Spain, United States

US States: MA, NY, 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.

FGFR2 mutation (continued)

NCT02608125
A Phase I Open-Label, Multicenter, Dose-Escalation Study of PRN1371, a FGFR I-IV Kinase Inhibitor, in Adult Patients With Advanced Solid Tumors, Followed by an Expansion Cohort in Patients With FGFR I, II, III, or IV Genetic Alterations

Cancer type: Unspecified Solid Tumor

Variant class: FGFR2 aberration

Other identifiers: NCI-2015-02144, PRN1371, PRN1371-001

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

Phase: I

Therapy: PRN-1371

Locations: Spain, United States

US State: TX

US Contact: Steven G Gourlay [650-416-7700]

NCT02966171
A Phase I, Open-label, Multi-center, Dose Escalation Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity of HMPL-453 in Patients With Advanced Solid Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: FGFR aberration

Other identifier: 2015-453-00AU1

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

Phase: I

Therapy: HMPL-453

Location: Australia

NCT01697605
A Phase I Study of Oral BGJ398 in Asian Patients with Advanced Solid Tumor Having Alterations of the FGF-R Pathway

Cancer type: Unspecified Solid Tumor

Variant class: FGFR aberration

Other identifiers: CBGJ398X1101, CTR20140515, JapicCTI-132280

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

Phase: I

Therapy: infigratinib

Location: Japan

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.

FBXW7 mutation

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: FBXW7 mutation

Other identifiers: 16-281, I4D-MC-E006, NCI-2016-01564

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]

NCT01037790
Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Unspecified Solid Tumor

Variant class: G1/S cell cycle pathway

Other identifiers: NCI-2009-01467, Study 1006, UPCC 03909, UPCC03909

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

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

US Contact: Peter O'Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

PIK3CA H1047R mutation

No NCT ID - see other identifier(s)
Molecular selection of therapy in metastatic colorectal cancer: a molecularly stratified randomised controlled trial programme

Cancer type: Colorectal Cancer

Variant class: PIK3CA mutation

Other identifiers: 14893, CR13, CRUK/11/054, EudraCT Number: 2012-005111-12, FOCUS-4, FOCUS4, IRAS ID 119459, ISRCTN90061546, MREC N° 13/SC/0111, UKCRN ID: 14893

Population segments: First line, Stage III, Stage IV

Phase: II/III

Therapies: MEK inhibitor + PIK3/mTOR inhibitor, PIK3/mTOR inhibitor

Location: United Kingdom

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

PIK3CA H1047R mutation (continued)

NCT02861300
Phase I/II Study of CB-839 and Capecitabine in Patients With Advanced Solid Tumors and Fluoropyrimidine Resistant PIK3CA Mutant Colorectal Cancer

Cancer type: Colorectal Cancer

Variant class: PIK3CA mutation

Other identifier: CASE1216

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

Phase: I/II

Therapy: CB-839 + chemotherapy

Location: United States

US State: OH

US Contact: Dr. Jennifer Eads [216-844-6031; jennifer.eads@uhhospitals.org]

NCT02912949
A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients With Solid Tumors

Cancer type: Colorectal Cancer

Variant class: PIK3CA mutation status

Other identifiers: EudraCT Number: 2014-003277-42, MCLA-128-CL01, NL51045.031.14

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

Phase: I/II

Therapy: MCLA-128

Locations: Netherlands, Spain

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

Cancer type: Colorectal Cancer

Variant class: PI3K/AKT/MTOR pathway

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

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 H1047R 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: PIK3CA activating 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: AZD-5363 + 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: PIK3CA mutation

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

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

Phase: II

Therapy: everolimus

Location: 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 identifier: 2014-10-030

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

Phase: II

Therapy: sirolimus

Location: Republic of Korea

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

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PIK3CA H1047R mutation (continued)

NCT02761694
A Phase I Dose Escalation Study of ARQ 751 in Adult Subjects With Advanced Solid Tumors With AKT1, 2, 3 Genetic Alterations, Activating PI3K Mutations or PTEN-null

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA activating mutation

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

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

Phase: I

Therapy: ARQ-751

Location: United States

US States: NV, TX

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

NCT02961283
A Phase I, Open-label, Dose-finding and Cohort Expansion Study of ASN003 in Subjects With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

Other identifier: ASN003-101

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

Phase: I

Therapy: ASN-003

Location: United States

US States: MI, TX

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

NCT01226316
A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients With Advanced Solid Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

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

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

Phase: I

Therapy: AZD-5363

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

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

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

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

PIK3CA H1047R mutation (continued)

NCT03006172
A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of GDC-0077 as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Hormone-Receptor Positive Breast Cancer

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

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

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

Phase: I

Therapy: GDC-0077

Location: United States

US States: MA, NY, TN

US Contact: Clinical Trials Hoffmann-La Roche [global.rochegenentechtrials@roche.com]

NCT02389842
PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With PAlbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA mutation

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

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

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Location: United Kingdom

NCT01971515
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PIK3CA aberration

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

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

Exclusion criteria variant classes: AKT2 amplification, AKT2 mutation

Phase: I

Therapy: MSC-2363318A

Location: United States

US States: AL, CA, FL, MI, NY, 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.

PIK3CA H1047R mutation (continued)

NCT02483858
Phase I Study of Oral PQR309 in Patients With Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

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

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

Phase: I

Therapy: PQR-309

Location: United States

US State: NY

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

TP53 mutation

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

Cancer type: Colorectal Cancer

Variant class: TP53 mutation

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

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

Phase: I

Therapy: pembrolizumab + p53MVA

Location: United States

US State: CA

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

NCT02042989
A Phase I Study of MLN9708 and Vorinostat to Target Autophagy in Patients With Advanced p53 Mutant Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 2013-0511, NCI-2014-01091

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

Phase: I

Therapy: ixazomib + vorinostat

Location: United States

US State: TX

US Contact: Dr. Siqing Fu [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.

TP53 mutation (continued)

NCT02610075
A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: D6015C00003, REFMAL 398

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

Phase: I

Therapy: MK-1775

Location: United States

US States: CO, TN

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

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

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

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

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.

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.

KRAS A146 mutation

Variant Class	Evidence Items
RAS/RAF/MEK/ERK pathway	4
↳ RAS mutation status	1
↳ RAS mutation	6
↳ KRAS mutation status	1
↳ KRAS mutation	30
↳ KRAS activating mutation	1
↳ KRAS A146 mutation	4
↳ KRAS exon 4 mutation	10
↳ KRAS A146 mutation	4
↳ RAS activating mutation	0
↳ KRAS activating mutation	1
↳ KRAS A146 mutation	4
↳ KRAS positive	1
↳ KRAS mutation	30
↳ KRAS activating mutation	1
↳ KRAS A146 mutation	4
↳ KRAS exon 4 mutation	10
↳ KRAS A146 mutation	4

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 (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.

MSH2 mutation

Variant Class	Evidence Items
DNA repair pathway	2
↳ MSH2 mutation	0
MMR pathway	5
↳ MSH2 mutation	0

FGFR2 mutation

Variant Class	Evidence Items
FGFR pathway	0
↳ FGFR aberration	4
↳ FGFR2 aberration	2
↳ FGFR2 positive	0
↳ FGFR2 mutation	2
↳ FGFR mutation	1
↳ FGFR2 mutation	2

FBXW7 mutation

Variant Class	Evidence Items
G1/S cell cycle pathway	1
↳ FBXW7 mutation	1

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 (continued)

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

PIK3CA H1047R mutation

Variant Class	Evidence Items
PI3K/AKT/MTOR pathway	2
↳ PIK3CA aberration	1
↳ PIK3CA mutation status	1
↳ PIK3CA mutation	8
↳ PIK3CA exon 20 mutation	0
↳ PIK3CA H1047R mutation	0
↳ PIK3CA activating mutation	2
↳ PIK3CA H1047R mutation	0

TP53 mutation

Variant Class	Evidence Items
TP53 mutation	6

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

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

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

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

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

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:
(a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;
(b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;
(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

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.

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

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

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

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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