[Oncofocus] Patient Test Report

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Surname		**Requesting clinician**	
Forename			
DOB		**Date requested**	
Gender	Male		
Histology #		**Tumour %**	35-40
Primary site	Pancreas	**Tumour % (macrodissected)**	
Tumour subtype	Adenocarcinoma		
Tissue type	Sternum		

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.

175 genes were targeted covering 2470 unique coding hot spots, 281 fusions and 19 CNV genes for actionable mutations linked to 484 anti-cancer targeted therapies.

The following actionable mutations 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	Alt allele Frequency	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
KRAS c.35G>T p.(Gly12Val)	21%	⊘ (3)	⊘ (2)	⊘ (4)	⊘ (3)	● (13)
MET(13)-MET(15) exon 14 skipping		✖	✖	✖	○ (1)	● (2)
TP53 c.637C>T p.(Arg213*)	29%	✖	✖	✖	✖	● (4)

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

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

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Relevant Therapy Summary

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

KRAS G12 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
cetuximab	⊘	⊘	⊘	⊘	✖
cetuximab + oxaliplatin	⊘	✖	✖	✖	✖
panitumumab + oxaliplatin	⊘	✖	✖	✖	✖
panitumumab	✖	⊘	⊘	⊘	✖
cetuximab + chemotherapy	✖	✖	⊘	✖	✖
panitumumab + chemotherapy	✖	✖	⊘	✖	✖
tyrosine kinase inhibitors	✖	✖	✖	⊘	✖
AZD-2014 + olaparib, AZD-5363 + olaparib, MK-1775 + olaparib, olaparib	✖	✖	✖	✖	● (II)
everolimus, lapatinib, nilotinib, pazopanib, sorafenib	✖	✖	✖	✖	● (II)
afatinib + selumetinib	✖	✖	✖	✖	● (I/II)
dacomitinib + PD-0325901	✖	✖	✖	✖	● (I/II)
lapatinib + trametinib + chemotherapy	✖	✖	✖	✖	● (I/II)
LNP3794	✖	✖	✖	✖	● (I/II)
palbociclib + PD-0325901	✖	✖	✖	✖	● (I/II)
alpelisib + binimetinib	✖	✖	✖	✖	● (I)
BAL-3833	✖	✖	✖	✖	● (I)
BGB-283	✖	✖	✖	✖	● (I)
CB-5083	✖	✖	✖	✖	● (I)
cobimetinib + duligotuzumab	✖	✖	✖	✖	● (I)
RO-5126766	✖	✖	✖	✖	● (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

MET exon 14 skipping mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
crizotinib	✖	✖	✖	○	✖
altiratinib	✖	✖	✖	✖	● (I)
MGCD-265	✖	✖	✖	✖	● (I)

TP53 mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
AZD-2014 + olaparib, AZD-5363 + olaparib, MK-1775 + olaparib, olaparib	✖	✖	✖	✖	● (II)
ixazomib + vorinostat	✖	✖	✖	✖	● (I)
MK-1775	✖	✖	✖	✖	● (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 2016-04-01. For the most up-to-date information, search www.ema.europa.eu/ema.

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:** 2016-04-15 **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 2016-04-01. For the most up-to-date information, search www.fda.gov.

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

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 G12 mutation (continued)

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

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 2.2016]

⊘ 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 1.2016]

⊘ 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 2.2016]

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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 1.2016]

⊘ tyrosine kinase inhibitors

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."
- "TKI therapy is not effective in patients with KRAS mutations and ALK gene rearrangements."

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

MET exon 14 skipping mutation

○ crizotinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** MET exon 14 skipping mutation

US-NCCN Recommendation category: 2A

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

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

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-03-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

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

Country: Netherlands

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

Country: 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 + chemotherapy

Country: Netherlands

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KRAS G12 mutation (continued)

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

Cancer type: Pancreatic Cancer

Variant class: KRAS mutation

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

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

Phase: I

Therapy: alpelisib + binimetinib

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

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

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

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

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

Country: United States

US State: CT

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

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

Therapies: everolimus, lapatinib, nilotinib, pazopanib, sorafenib

Country: 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.

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

Country: United States

US State: MA

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

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

Cancer type: Unspecified Solid Tumor

Variant class: RAS mutation

Other identifier: TrialTroveID-250171

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

Phase: I/II

Therapy: LNP3794

Country: United Kingdom

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

Cancer type: Unspecified Solid Tumor

Variant class: KRAS mutation

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

Population segments: First line, Stage III, Stage IV

Phase: I

Therapy: BGB-283

Countries: Australia, New Zealand

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

KRAS G12 mutation (continued)

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 Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: KRAS mutation

Other identifiers: 149511, CLC-101, TrialTroveID-216163

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

Phase: I

Therapy: CB-5083

Country: United States

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

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

NCT01986166
A Phase Ib, Open-Label, Dose-Escalation Study of The Safety, Tolerability, and Pharmacokinetics Of MEHD7945A and GDC-0973 In Patients with Locally Advanced or Metastatic Solid Tumors with Mutant Kras

Cancer type: Unspecified Solid Tumor

Variant class: KRAS mutation

Other identifiers: EudraCT Number: 2013-001910-14, GO29030, STU 112013-082, TrialTroveID-196701, VICCPHI1387

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

Phase: I

Therapy: cobimetinib + duligotuzumab

Country: United States

US State: CT

US Contact: Reference Study ID Number: GO29030 [888-662-6728; global.rochegenentechtrials@roche.com]

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

Phase: I

Therapy: RO-5126766

Country: United Kingdom

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

KRAS G12 mutation (continued)

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

Cancer type: Unspecified Solid Tumor

Variant class: RAS mutation

Other identifiers: 4232, PanRAF, TrialTroveID-257046

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

Phase: I

Therapy: BAL-3833

Country: United Kingdom

MET exon 14 skipping mutation

NCT00697632
Open-Label Dose-Escalation Trial to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Daily Oral MGCD265 Administered Without Interruption to Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: MET fusion

Other identifiers: 00005540, 00009948, 2012-0741, 20142263, 265-101, AAAP0559, DFCI 08-007, MGCD265-101, MIRATI265-101, NCI-2010-00030, P1TMG265, Trial 101, TrialTroveID-081814, UCI-13-49, UW13036

Population segments: Advanced, Bone mets, Hormone refractory, Liver mets, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV, Unresectable

Phase: I

Therapy: MGCD-265

Countries: Canada, Republic of Korea, United States

US States: CA, IL, MA, MO, NC, NY, PA, TX, UT, WA

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

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MET exon 14 skipping mutation (continued)

NCT02228811
A Multicenter Phase I Ascending Dose Study of DCC-2701 To Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: MET aberration

Other identifiers: 14-031, 2014-0878, DCC-2701-01-001, NCI-2014-02040, TrialTroveID-201122, VICCPHI13113

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

Phase: I

Therapy: altiratinib

Country: United States

US States: CO, MA, PA, TN, TX

US Contact: Linda M. Martin [785-830-2100; lmartin@deciphera.com]

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 class: TP53 mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

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

Phase: II

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

Country: United States

US State: CT

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

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, TrialTroveID-201319

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

Phase: I

Therapy: ixazomib + vorinostat

Country: 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.

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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, TrialTroveID- 268385

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

Phase: I

Therapy: MK-1775

Country: 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: SGT53-01-2, TrialTroveID-251586

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

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Country: United States

US State: TX

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

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

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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 G12 mutation

Variant Class	Evidence Items
RAS mutation	2
↳ RAS activating mutation	0
↳ KRAS G12 mutation	2
↳ KRAS mutation	15
↳ KRAS exon 2 mutation	9
↳ KRAS G12 mutation	2

MET exon 14 skipping mutation

Variant Class	Evidence Items
MET aberration	1
↳ MET positive	0
↳ MET fusion	1
↳ MET exon 14 skipping mutation	1

TP53 mutation

Variant Class	Evidence Items
TP53 aberration	0
↳ TP53 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.

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

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6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

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.

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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:

(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.

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.


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