[Oncofocus] Patient Test Report

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Histology #		**Tumour %**	60
Primary site	Unknown	**Tumour % (macrodissected)**	
Tumour subtype	Cup		
Tissue type	Lymph Node		

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. Considering the cancer is of an unknown origin, this report encompasses the entire scope of linkages for the below variants. Please note that some of the linkages to clinical trials are tumour type specific.

Variant Summary

Sample Cancer Type: Cancer of unknown primary

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

Gene Variant	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
MET amplification	✖	✖	✖	● (1)	● (30)
MET(13)-MET(15) exon 14 skipping	✖	✖	✖	● (1)	● (8)
CDK6 amplification	✖	✖	✖	✖	● (2)

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

MET amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
crizotinib	✖	✖	✖	●	● (II)
erlotinib	✖	✖	✖	✖	● (IV)
alpelisib, binimetinib, capmatinib, ceritinib, luminespib	✖	✖	✖	✖	● (II)
capmatinib	✖	✖	✖	✖	● (II)
capmatinib + nivolumab, EGF-816 + nivolumab	✖	✖	✖	✖	● (II)
erlotinib + chemotherapy	✖	✖	✖	✖	● (II)
MGCD-265	✖	✖	✖	✖	● (II)
SAR-125844	✖	✖	✖	✖	● (II)
capmatinib + gefitinib	✖	✖	✖	✖	● (I/II)
gefitinib + tepotinib	✖	✖	✖	✖	● (I/II)
altiratinib	✖	✖	✖	✖	● (I)
capmatinib + erlotinib	✖	✖	✖	✖	● (I)
crizotinib + chemotherapy, crizotinib + pazopanib, crizotinib + pazopanib + chemotherapy	✖	✖	✖	✖	● (I)
crizotinib + dasatinib	✖	✖	✖	✖	● (I)
gefitinib + volitinib	✖	✖	✖	✖	● (I)
MGCD-516	✖	✖	✖	✖	● (I)
volitinib	✖	✖	✖	✖	● (I)
bevacizumab + capmatinib	✖	✖	✖	✖	● (I)
volitinib	✖	✖	✖	✖	● (II)
volitinib + chemotherapy	✖	✖	✖	✖	● (I/II)
crizotinib + PD-0325901	✖	✖	✖	✖	● (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.

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 (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-MET fusion

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
crizotinib	✖	✖	✖	●	✖
capmatinib + nivolumab, EGF-816 + nivolumab	✖	✖	✖	✖	● (II)
altiratinib	✖	✖	✖	✖	● (I)
gefitinib + volitinib	✖	✖	✖	✖	● (I)
MGCD-265	✖	✖	✖	✖	● (I)
MGCD-516	✖	✖	✖	✖	● (I)
crizotinib + PD-0325901	✖	✖	✖	✖	● (I)
bevacizumab + capmatinib	✖	✖	✖	✖	● (I)
crizotinib	✖	✖	✖	○	● (II)
buparlisib + capmatinib	✖	✖	✖	✖	● (I/II)

CDK6 amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
AZD4547 + chemotherapy, durvalumab, erlotinib, erlotinib + rilotumumab, palbociclib, taselisib	✖	✖	✖	✖	● (II/III)
ribociclib	✖	✖	✖	✖	● (II)
buparlisib + capmatinib	✖	✖	✖	✖	● (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.

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

Current 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 2015-11-17. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

MET amplification

● crizotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

US-NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 1.2016]

MET-MET fusion

● 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 1.2016]

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

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2015-11-02. 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'.

MET amplification

NCT01523340
Phase IV Study of Response to EGFR-TKI and Correlation With C-met Expression and EGFR Gene Mutation in NSCLC Patients Treated With Erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: MENTOR, MENTOR_2011, TrialTroveID-161434

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

Phase: IV

Therapy: erlotinib

Country: Republic of Korea

NCT02276027
A Phase II, Open Label, Multiple Arm Study of Single Agent AUY922, BYL719, INC280, LDK378 and MEK162 in Chinese Patients With Advanced Non-small Cell Lung Cancer (NSCLC)

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: CINC280X2205, CTR20140725, TrialTroveID-209048

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

Phase: II

Therapies: alpelisib, binimetinib, capmatinib, ceritinib, luminespib

Country: China

NCT02414139
A Phase II, Multicenter, Three-cohort Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type (wt), Advanced Non-small Cell Lung Cancer (NSCLC) Who Have Received One or Two Prior Lines of Systemic Therapy for Advanced/Metastatic Disease

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: CINC280A2201, EudraCT Number: 2014-003850-15, TrialTroveID-255286

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

Exclusion criteria variant classes: EGFRi sensitizing mutation, ALK fusion

Phase: II

Therapy: capmatinib

Countries: Lebanon, Singapore

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

MET amplification (continued)

NCT02034981
AcSé CRIZOTINIB : Secured Access to Crizotinib for Patients With Tumors Harboring a Genomic Alteration on One of the Biological Targets of the Drug

Cancer type: Colorectal Cancer, Esophageal Cancer, Gastric Cancer, Glioblastoma, Kidney Cancer, Liver Cancer, Non-Small Cell Lung Cancer,

Variant class: MET amplification

Other identifiers: AcSé, AcSé CRIZOTINIB, EudraCT Number: 2013-000885-13, FSCA-crizotinib, TrialTroveID-200633, UC-0105/1303

Population segments: Aggressive, Anaplastic, Follicular, Line of therapy N/A, Medullary, Papillary, Pediatric or Adolescent, Peripheral T-cell lymphoma (PTCL), Stage III, Stage IV

Exclusion criteria variant class: ALK fusion

Phase: II

Therapy: crizotinib

Country: France

NCT02499614
Crizotinib in Pretreated Metastatic Non-small-cell Lung Cancer With MET Amplification or ROS1 Translocation (METROS)

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: EudraCT Number: 2014-001263-12, FoRT 01/2014, IEO 189, METROS, TrialTroveID-250290

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

Phase: II

Therapy: crizotinib

Country: Italy

NCT02098954
Second Line Erlitinib Combination With Gemcitabine Cisplatinum in Non-small Cell Lung Cancer Patients Who Harbored EGFR Sensitive Mutation Developed Resistance After First Line TKI Treatment

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: TKIRR001, TrialTroveID-205762

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

Phase: II

Therapy: erlotinib + chemotherapy

Country: China

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

MET amplification (continued)

NCT02544633
Phase II, Parallel-Arm Study of MGCD265 in Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With Activating Genetic Alterations in Mesenchymal-Epithelial Transition Factor

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: 265-109, TrialTroveID-257006

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

Exclusion criteria variant classes: EGFR mutation, ALK fusion

Phase: II

Therapy: MGCD-265

Country: United States

US States: CA, MI

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

NCT02435121
Phase II, Open Label, Single Arm Study Assessing the Clinical Benefit of SAR125844, Administered as Single Agent by Weekly Intravenous (IV) Infusion, for the Treatment of Patients With Advanced Pretreated Non-Small Cell Lung Cancer (NSCLC) Harboring MET Gene Amplification

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: ACT14205, EudraCT Number: 2014-005696-93, TrialTroveID-257010, U1111-1163-1136

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

Phase: II

Therapy: SAR-125844

Countries: Australia, Belgium, Bulgaria, Canada, Czech Republic, France, Hungary, Israel, Italy, Japan, Netherlands, Republic of Korea, Romania, Spain

NCT02323126
A Phase II, Multicenter, Open-label Study of EGF816 in Combination with Nivolumab in Adult Patients with EGFR Mutated Non-small Cell Lung Cancer and of INC280 in Combination with Nivolumab in Adult Patients with cMet Positive Non-small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET positive

Other identifiers: CEGF816X2201C, EudraCT Number: 2014-003731-20, TrialTroveID-218316

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

Phase: II

Therapies: capmatinib + nivolumab, EGF-816 + nivolumab

Country: Singapore

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

MET amplification (continued)

NCT01610336
A Phase IB/II, Open Label, Multicenter Study of INC280 Administered Orally in Combination With Gefitinib in Adult Patients With EGFR Mutated, c-MET-amplified Non-small Cell Lung Cancer Who Have Progressed After EGFR Inhibitor Treatment

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: CINC280X2202, CTR20132495, EudraCT Number: 2011-002569-39, TrialTroveID-169016

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

Phase: I/II

Therapy: capmatinib + gefitinib

Countries: Australia, Belgium, China, France, Germany, Israel, Italy, Japan, Netherlands, Republic of Korea, Singapore, Spain, Taiwan, Thailand

NCT01982955
A Phase Ib/II Multicenter, Randomized, Open Label Trial to Compare MSC2156119J Combined With Gefitinib Versus Chemotherapy as Second-line Treatment in Subjects With MET Positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) Harboring EGFR Mutation and Having Acquired Resistance to First-line Gefitinib

Cancer type: Glioblastoma, Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: 200095-006, CTR20150252, EMR200095-006, TrialTroveID-197167

Population segments: Adenocarcinoma, EGFR, Large Cell, Other subtype, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapy: gefitinib + tepotinib

Country: Germany

NCT01324479
A Phase I Open-label Dose Escalation Study with Expansion to assess the Safety and Tolerability of INC280 in Patients with c-MET Dependent Advanced Solid Tumors

Cancer Type: BladderCancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, GIST, Glioblastoma, Head and Neck Cancer, Kideny Cancer, Liver Cancer, Melanoma, Mesothelioma, Non-Small cell Lung Cancer, Osteosarcoma, Pancreatic Cancer, Prostate Cancer, Skin Basal Cell Sarcoma, Small Cell Lung Cancer, Soft Tissue Sarcoma, Testicular Cancer, Thyroid Cancer

Variant class: MET amplification

Other identifiers: 13-0171, 201104009MA, ACT004, CINC280X2102, EudraCT Number: 2010-024101-12, HKCTR-1720, MDACC 2012-0985, NL43000.031.12, REFMAL 291 IST, TrialTroveID-144387

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

Exclusion criteria variant class: EGFR mutation

Phase: I

Therapy: capmatinib

Countries: Australia, Canada, Germany, Hong Kong, Italy, Netherlands, Republic of Korea, Singapore, Spain, Taiwan, United States

US States: IL, TN, TX

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

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

MET amplification (continued)

NCT01911507
Phase I Study of INC280 Plus Erlotinib in Patients With C-Met Expressing Non-Small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET amplification

Other identifiers: CINC280XUS02T, TrialTroveID-191184, UCDCC#238

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

Phase: I

Therapy: capmatinib + erlotinib

Country: United States

US State: CA

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

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: Bladder Cancer, Colorectal Cancer, Esophageal Cancer, Gastic Cancer, GIST, Glioblastoma, Head and Neck Cancer, Kidney Cancer, Liver Cancer, Melanoma, Kidney Cancer, Melanoma, Mesothelioma, Non-Small Cell Lung Cancer, Osteosarcoma, Pancreatic, Prostate Cancer, Skin Basal Cell Sarcoma, Small Cell Lung Cancer, Soft Tissue Sarcoma, Thyroid Cancer, Testicular Cancer

Variant class: MET amplification

Other identifiers: 00005540, 00009948, 20142263, 265-101, AAAP0559, DFCI 08-007, MGCD265-101, P1TMG265, Trial 101, TrialTroveID-081814

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]

NCT01391533
Dose Escalation, Safety, Pharmacokinetic and Pharmacodynamic, First in Man Study, of SAR125844 Single Agent Administered as Slow Intravenous Infusion in Adult Patients With Advanced Malignant Solid Tumors

Cancer Type: Bladder Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, GIST, Glioblastoma, Head and Neck cancer, Kidney Cancer, Liver Cancer, Melanoma, Mesothelioma, Non-Small Cell Lung Cancer, Osteosarcoma, Pancreatic, Prostate Cancer, Skin Basal Cell Sarcoma, Small Cell Lung Cancer, Soft Tissue Sarcoma, Tyroid Cancer, Testicular Cancer.

Variant class: MET amplification

Other identifiers: EudraCT Number: 2010-021398-36, IEO S597/111, RECF2367, Sanofi TED11449 SARMET, SARMET, TED11449, TrialTroveID-149908, U1111-1117-9878

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

Phase: I

Therapy: SAR-125844

Countries: France, Italy, Spain, United States

US State: MA

US Contact: Clinical Sciences & Operations Sanofi-Aventis [Contact-Us@sanofi.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.

MET amplification (continued)

NCT01985555
A Phase I, Open-label, Multicenter Dose-escalation Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity of Volitinib in Patients With Advanced Solid Tumors

Cancer Type: Bladder Cancer, CRC, Esophageal Cancer, Gastric Cancer, GIST, Glioblastoma, Head and Neck Cancer, Kidney Cancer, Liver Cancer, Melanoma, Mesothelioma, Non-Small Cell Lung Cancer, Osteosarcoma, Pancreatic, Prostate Cancer, Small Cell Lung Cancer, Skin Baal Cell Carcinoma, Soft Tissue Sarcoma, Thyroid Cancer, Testicular Cancer.

Variant class: MET amplification

Other identifiers: 2011-504-00CH1, TrialTroveID-188988

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

Phase: I

Therapy: volitinib

Country: China

NCT02374645
A Phase Ib, Open-label, Multi-centre Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumour Activity of Volitinib in Combination With Gefitinib (Iressa) in Patients With Epidermal Growth Factor Receptor-mutated Non-small Cell Lung Cancer Who Have Progressed on Epidermal Growth Factor Receptor Inhibitor Treatment

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET positive

Other identifiers: CTR20140879, D5080C00001, TrialTroveID-253097

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: gefitinib + volitinib

Country: China

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

Cancer type: Head and Neck Cancer, Non-Small Cell Lung Cancer

Variant class: MET aberration

Other identifiers: 516-00, AAAO0006, TrialTroveID-197300

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

Phase: I

Therapy: MGCD-516

Country: United States

US States: MA, MO, NY, TN, UT

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

MET amplification (continued)

NCT01548144
A Two Steps Phase I Trial of Pazopanib or Pemetrexed in Combination With Crizotinib Followed by the Triplet, Crizotinib Plus Pazopanib Plus Pemetrexed in Patients With Advanced Malignancies

Cancer type: Unspecified Cancer

Variant class: MET amplification

Other identifiers: 2011-1142, NCI-2012-00324, TrialTroveID-163762

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

Phase: I

Therapies: crizotinib + chemotherapy, crizotinib + pazopanib, crizotinib + pazopanib + chemotherapy

Country: United States

US State: TX

US Contact: Dr Ralph Zinner [800-392-1611]

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

Cancer type: Unspecified Solid Tumor

Variant class: MET amplification

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

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

Phase: I

Therapy: crizotinib + dasatinib

Country: United States

US State: TX

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

NCT01657214
Phase I, Dose Escalation Study of Safety, Pharmacokinetic and Pharmaco-Dynamic of SAR125844 Administered Weekly as Intravenous Infusion in Asian Adult Patients With Advanced Malignant Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: MET amplification

Other identifiers: SARMETA, TED12337, TrialTroveID-172382, U1111-1126-7527

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

Phase: I

Therapy: SAR-125844

Countries: Japan, 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.

MET amplification (continued)

NCT02228811
A Multicenter Phase IA/IB 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: 2014-0878, DCC-2701-01-001, 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]

NCT02386826
Phase Ib Study Evaluating the c-Met Inhibitor INC280 in Combination With Bevacizumab in Glioblastoma Multiforme (GBM), Metastatic Colorectal Cancer
(mCRC) and Metastatic Renal Cell Carcinoma (mRCC) Patients

Cancer type: Colorectal Cancer, Glioblastoma, Kidney Cancer.

Variant class: MET amplification

Other identifiers: SCRI REFMAL 365, TrialTroveID-253602

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

Therapy: bevacizumab + capmatinib

Country: United States

US States: CO, TN

US Contact: Sarah Cannon Research Institute [877-691-7274; asksarah@scresearch.net]

NCT02510001
A Phase 1 Study of MEK 1/2 Inhibitor PD-0325901 With cMET Inhibitor PF-03241066 in RASMT and RASWT (With Aberrant c-MET) Colorectal Cancer Patients

Cancer type: Colorectal Cancer

Variant class: MET aberration

Other identifiers: 17363, EudraCT number: 2014-000463-40, ISRCTN18043777, MErCuRIC, MErCuRIC1, OCTO-049, TrialTroveID-217604, UKCRN ID:17363

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

Phase: I

Therapy: crizotinib + PD-0325901

Countries: Belgium, Czech Republic, France, Ireland, Italy, Spain, 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.

MET amplification (continued)

NCT02449551
Study of AZD6094 (Volitinib) in Advanced Gastric Adenocarcinoma Patients With MET Amplification as a Third-line Treatment

Cancer type: Esophageal Cancer, Gastric Cancer.

Variant class: MET amplification

Other identifiers: 2014-07-167, TrialTroveID-257789

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

Phase: II

Therapy: volitinib

Country: Republic of Korea

NCT02435108
A Pilot Study of Crizotinib in Patients With c-MET Positive Gastric Adenocarcinoma as a Third-line Chemotherapy

Cancer type: Esophageal Cancer, Gastric Cancer,

Variant class: MET positive

Other identifiers: 2014-03-117-003, TrialTroveID-257025

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

Phase: II

Therapy: crizotinib

Country: Republic of Korea

NCT02447406
Study of AZD6094 (Volitinib) in Combination With Docetaxel, in Advanced Gastric Adenocarcinoma Patients With MET Amplification as a Second-line Treatment

Cancer type: Esophageal Cancer, Gastric Cancer

Variant class: MET amplification

Other identifiers: 2014-07-169, TrialTroveID-257679

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

Exclusion criteria variant class: ERBB2 amplification

Phase: I/II

Therapy: volitinib + chemotherapy

Country: Republic of Korea

No NCT ID - see other identifier(s)
A Phase Ib, Efficacy Study of Savolitinib as a Monotherapy in c-Met Amplified Gastric Cancer Patients

Cancer type: Gastric Cancer

Variant class: MET amplification

Other identifiers: Study 9, TrialTroveID-263342

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

Phase: I

Therapy: volitinib

Country: China

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

MET amplification (continued)

No NCT ID - see other identifier(s)
A Phase Ib, Dose Finding Study of Savolitinib in Combination with Docetaxel in c-Met Amplified, First Line Gastric Cancer Patients

Cancer type: Gastric Cancer

Variant class: MET amplification

Other identifiers: Study 11, TrialTroveID-263335

Population segments: (N/A), First line

Phase: I

Therapy: volitinib + chemotherapy

Country: China

NCT01870726
A Phase Ib/II, Multi-center, Open-label Study of Single-agent INC280 or in Combination With Buparlisib in Patients With Recurrent Glioblastoma

Cancer type: Glioblastoma

Variant class: MET amplification

Other identifiers: 13-501, 2013-0632, AAAM3463, CINC280X2204, Eudract Number: 2013-000699-14, NL45781.041.13, Novartis INC280, REec-2013-0630, SAKK 66/13, TrialTroveID-188051

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

Phase: I/II

Therapy: buparlisib + capmatinib

Countries: Germany, Netherlands, Spain, Switzerland, United States

US States: NC, 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.

MET-MET fusion

NCT02323126
A Phase II, Multicenter, Open-label Study of EGF816 in Combination with Nivolumab in Adult Patients with EGFR Mutated Non-small Cell Lung Cancer and of INC280 in Combination with Nivolumab in Adult Patients with cMet Positive Non-small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET positive

Other identifiers: CEGF816X2201C, EudraCT Number: 2014-003731-20, TrialTroveID-218316

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

Phase: II

Therapies: capmatinib + nivolumab, EGF-816 + nivolumab

Country: Singapore

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: Bladder Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, GIST, Glioblastoma, Head and Neck Cancer, Kidney Cancer, Liver Cancer, Melanoma, Mesothelioma, Non-Small Cell Lung Cancer, Osteosarcoma, Pancreatic Cancer, Prostate Cancer, Skin Basal Cell Sarcoma, Small Cell Lung Cancer, Soft Tissue Sarcoma, Thyroid Cancer, Testicular Cancer.

Variant class: MET fusion

Other identifiers: 00005540, 00009948, 20142263, 265-101, AAAP0559, DFCI 08-007, MGCD265-101, P1TMG265, Trial 101, TrialTroveID-081814

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]

NCT02510001
A Phase 1 Study of MEK 1/2 Inhibitor PD-0325901 With cMET Inhibitor PF-03241066 in RASMT and RASWT (With Aberrant c-MET) Colorectal Cancer Patients

Cancer type: Colorectal Cancer

Variant class: MET aberration

Other identifiers: 17363, EudraCT number: 2014-000463-40, ISRCTN18043777, MErCuRIC, MErCuRIC1, OCTO-049, TrialTroveID-217604, UKCRN ID:17363

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

Phase: I

Therapy: crizotinib + PD-0325901

Countries: Belgium, Czech Republic, France, Ireland, Italy, Spain, United Kingdom

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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.

MET-MET fusion (continued)

NCT02374645
A Phase Ib, Open-label, Multi-centre Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumour Activity of Volitinib in Combination With Gefitinib (Iressa) in Patients With Epidermal Growth Factor Receptor-mutated Non-small Cell Lung Cancer Who Have Progressed on Epidermal Growth Factor Receptor Inhibitor Treatment

Cancer type: Non-Small Cell Lung Cancer

Variant class: MET positive

Other identifiers: CTR20140879, D5080C00001, TrialTroveID-253097

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: gefitinib + volitinib

Country: China

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

Cancer type: Head and Neck Cancer, Non-Small Cell Lung Cancer

Variant class: MET aberration

Other identifiers: 516-00, AAAO0006, TrialTroveID-197300

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

Phase: I

Therapy: MGCD-516

Country: United States

US States: MA, MO, NY, TN, UT

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

NCT02228811
A Multicenter Phase IA/IB 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: 2014-0878, DCC-2701-01-001, 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]

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.

MET-MET fusion (continued)

NCT02435108
A Pilot Study of Crizotinib in Patients With c-MET Positive Gastric Adenocarcinoma as a Third-line Chemotherapy

Cancer type: Esophageal Cancer, Gastric Cancer

Variant class: MET positive

Other identifiers: 2014-03-117-003, TrialTroveID-257025

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

Phase: II

Therapy: crizotinib

Country: Republic of Korea

NCT01870726
A Phase Ib/II, Multi-center, Open-label Study of Single-agent INC280 or in Combination With Buparlisib in Patients With Recurrent Glioblastoma

Cancer type: Glioblastoma

Variant class: MET fusion

Other identifiers: 13-501, 2013-0632, AAAM3463, CINC280X2204, Eudract Number: 2013-000699-14, NL45781.041.13, Novartis INC280, REec-2013-0630, SAKK 66/13, TrialTroveID-188051

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

Phase: I/II

Therapy: buparlisib + capmatinib

Countries: Germany, Netherlands, Spain, Switzerland, United States

US States: NC, NY, TX

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

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

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CDK6 amplification

NCT02154490
S1400 Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: CDK6 amplification

Other identifiers: 14.1077, 1407538042, 14203, ECOG-ACRIN S1400, Lung-MAP, Master Lung-1, NCG 260614, NCI-2014-00627, S1400, S1400A, S1400B, S1400C, S1400D, S1400E, SWOG1400, SWOG1400A, SWOG1400B, SWOG1400C, SWOG1400D, SWOGS1400, TrialTroveID-198766

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

Exclusion criteria variant classes: ALK fusion, EGFR mutation

Phase: II/III

Therapies: AZD4547 + chemotherapy, durvalumab, erlotinib, erlotinib + rilotumumab, palbociclib, taselisib

Country: United States

US States: AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MT, NC, ND, NE, NH, NJ, 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.

NCT02187783
ModularPhaseIIStudytoLinkTargeted TherapytoPatientswithPathway ActivatedTumors:Module8-LEE011for PatientswithCDK4/6PathwayActivated Tumors

Cancer type: Bladder Cancer, Colorectal Cancer, Esophageal Cancer, Gastric Cancer, GIST, Glioblastoma, Head and Neck Cancer, Kidney Cancer, Liver Cancer, Mesothelioma, Non-SmallCell Lung Cancer, Osteosarcoma, Pancreatic Cancer, Prostate Cancer, Skin Basal Cell Sarcoma, Small Cell Lung Cancer, Thyroid Cancer, Testicular Cancer.

Variant class: CDK6amplification

Other identifiers: 051501, 2014-0689, CLEE011XUS03, SIGNATURE, TrialTroveID-212878

Population segments: Aggressive, Cutaneous T-cell lymphoma (CTCL), Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), HER2 negative, Indolent, Lymphoblastic lymphoma (LBL), Other subtype, Peripheral T-cell lymphoma (PTCL), Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Triple receptor negative, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: ribociclib

Country: United States

US States: AK, AZ, CA, CT, GA, IN, LA, MD, MO, NC, NM, OH, OR, RI, SD, TN, TX, UT, VA, WA, WI

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.

Terms and Conditions

The following paragraph on Liability is an extract from the Oncologica Tests' Terms and Conditions. The extract is to draw your attention to particular terms applicable to you but nothing set out here is intended to supersede or override our Terms and Conditions, which can be found on our website at www.oncologica.com under the title Oncologica Tests' Terms and Conditions. Please read these Oncologica Test Terms and Conditions carefully before you submit an order for the Oncologica Tests, as you will be bound by these Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.

6. Liability

6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

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.

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.

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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