



[Oncofocus] Patient Test Report

Histology #		Tumour %	60
Primary site	Unknown	Tumour %	
Tumour subtype	Cup	(macrodissected)	
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.

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.

www.oncologica.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.

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.

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]

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 AUJ922, 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

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 Erlotinib 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

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

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: 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, 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]

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, UCDC#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, Gastric 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, Thyroid 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]

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 Basal 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]

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 Pharmacodynamic 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

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

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

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]

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 With or 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

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]

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]

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.

