Taipei Veterans General Hospital

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Sample Information

Patient Name:
Gender: Male
ID No.: A123740357
History No.: 33237160
Age: 64

Ordering Doctor: DOC3153J
Ordering REQ.: 0ARJYYF
Signing in Date: 2020/04/27

Path No.: S109-99390
MP No.: F20015
Assay: Oncomine Focus Assay
Sample Type: FFPE
Block No.: S109-12958A
Percentage of tumor cells: 50%

Reporting Doctor:

Note:

Sample Cancer Type: Non-Small Cell Lung Cancer

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Relevant Non-Small Cell Lung Cancer Variants

Gene	Finding	Gene	Finding
ALK	None detected	NTRK1	None detected
BRAF	None detected	NTRK2	None detected
EGFR	None detected	NTRK3	None detected
ERBB2	None detected	RET	None detected
KRAS	None detected	ROS1	None detected
MET	***MET exon 14 skipping***		

Relevant Biomarkers

Tier	Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
IA	*MET exon 14 skipping* MET proto-oncogene, receptor tyrosine kinase **Prognostic significance:** None **Diagnostic significance:** None	**capmatinib** [1] **tepotinib** [1] crizotinib	None	30
IIC	*JAK3 p.(S493C) c.1477A>T* Janus kinase 3 Allele Frequency: 3.41% **Prognostic significance:** None **Diagnostic significance:** None	None	None	1

Public data sources included in relevant therapies: FDA[1], NCCN, **EMA**[2], ESMO
Public data sources included in prognostic and diagnostic significance: NCCN, ESMO
Tier Reference: Li et al. *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists.* J Mol Diagn. 2017 Jan;19(1):4-23.

Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect	Coverage
JAK3	p.(S493C)	c.1477A>T	COSM48455	chr19:17949164	3.41%	NM_000215.3	missense	1997
JAK1	p.(=)	c.2199A>G	.	chr1:65310489	55.44%	NM_002227.3	synonymous	1995
ALK	p.(D1529E)	c.4587C>G	.	chr2:29416366	63.60%	NM_004304.4	missense	1665
ALK	p.(I1461V)	c.4381A>G	.	chr2:29416572	99.95%	NM_004304.4	missense	2000
ALK	p.(=)	c.3375C>A	.	chr2:29445458	58.25%	NM_004304.4	synonymous	1885
FGFR3	p.(N262D)	c.784A>G	.	chr4:1803606	7.23%	NM_000142.4	missense	1993
FGFR3	p.(=)	c.1953G>A	.	chr4:1807894	99.75%	NM_000142.4	synonymous	1997
PDGFRA	p.(=)	c.1701A>G	.	chr4:55141055	99.92%	NM_006206.5	synonymous	1244
FGFR4	p.(P136L)	c.407C>T	.	chr5:176517797	99.10%	NM_213647.2	missense	2000
SMO	p.(V411L)	c.1231G>C	.	chr7:128846395	8.71%	NM_005631.4	missense	1998
FGFR1	p.(=)	c.2178T>G	.	chr8:38271771	9.52%	NM_001174067.1	synonymous	1229
RET	p.(=)	c.2307G>T	.	chr10:43613843	44.57%	NM_020975.4	synonymous	1999
RET	p.(=)	c.2712C>G	.	chr10:43615633	39.23%	NM_020975.4	synonymous	678
MAP2K1	p.(Y134F)	c.401A>T	.	chr15:66729193	12.56%	NM_002755.3	missense	1999

Gene Fusions (RNA)

Genes	Variant ID	Locus	Read Count
MET-MET	MET-MET.M13M15	chr7:116411708 - chr7:116414935	24110

Biomarker Descriptions

JAK3 (Janus kinase 3)

Background: The JAK3 gene encodes a non-receptor, membrane associated protein tyrosine kinase (PTK). JAK3 is a member of the Janus kinase (JAK) family that includes JAK1, JAK2, JAK3, and TYK2. Janus kinases are characterized by the presence of a second phosphotransferase-related or pseudokinase domain immediately N-terminal to the PTK domain[1]. JAK kinases function with signal transducer and activator of transcription (STAT) proteins to facilitate intracellular signal transduction required for cytokine receptor and interferon-alpha/beta/gamma signaling[1,2,3].

Alterations and prevalence: Recurrent somatic mutations in JAK3 have been observed in T-cell lymphomas and acute lymphoblastic leukemia (ALL)[4,5]. Mutations in the pseudokinase domain (M511I, A573V, R657W), and kinase domain (L857Q) activate the JAK/STAT pathway and transform hematopoietic cells in vitro[4]. These variants are infrequently observed in solid cancers[6].

Potential relevance: Currently, no therapies are approved for JAK3 aberrations. Tofacitinib (2012) is a JAK3 inhibitor FDA approved for rheumatoid and psoriatic arthritis. Activating mutations in JAK3, including the germline variant V722I, promoted increased expression of PD-L1 in lung cancer and were associated with durable benefit from tofacitinib PD-L1 blockade[7].

MET (MET proto-oncogene, receptor tyrosine kinase)

Background: The MET proto-oncogene encodes a receptor tyrosine kinase for the hepatocyte growth factor (HGF) protein, which is expressed by mesenchymal cells. MET is expressed as multiple isoforms with transcript variant 1 (NM_001127500.3) encoding a 1408 amino acid protein and transcript variant 2 (NM_000245.4) encoding a 1390 amino acid protein, both of which possess an intact protein kinase domain[8]. Ubiquitin-dependent proteolysis is responsible for regulating the steady state level of the MET protein via recognition of the tyrosine phosphorylation site Y1003(NM_000245.4), sometimes referred to as Y1021 (NM_001127500.3), in the MET Cbl-binding domain within the juxtamembrane region[9,10,11]. Growth factor signaling leads to MET dimerization and subsequent initiation of downstream effectors including those involved in the RAS/RAF/MEK/ERK and PI3K/AKT signaling pathways, which regulate cell migration, proliferation, and survival[12,13].

Alterations and prevalence: Somatic mutations in MET are observed in 10% of uterine corpus endometrial carcinoma, 9% of skin cutaneous melanoma, 8% of papillary renal cell carcinoma (PRCC), and 4% of lung adenocarcinoma, colorectal adenocarcinoma, bladder urothelial carcinoma, and uterine carcinosarcoma[6,14]. Recurrent somatic MET alterations include activating mutations, gene amplification, and translocations generating MET gene fusions. Recurrent somatic mutations fall into two classes, mutations in the MET kinase domain, which are uncommon, and splice-site mutations affecting exon 14. Recurrent kinase domain mutations are observed in PRCC and include M1250T, H1094Y, and V1070E (NM_000245.4)[6,14]. Mutation of the Y1003 phosphorylation site is reported in approximately 2% of MET altered lung cancer[15]. In contrast, splice-site mutations flanking exon 14 are observed in 3-4% of all non-small cell lung cancer (NSCLC)[16]. These mutations include canonical splice site mutations affecting exon 14 and deletions that extend into the splicing motifs within intron 13[15,17]. Such mutations disrupt splicing leading to the formation of an alternative transcript that joins exon 13 directly to exon 15 and skips exon 14 entirely. The MET exon 14 skipping transcript lacks the juxtamembrane domain that contains the recognition motif for ubiquitin-dependent proteolysis and thus leads to a marked increase in the steady-state level of the MET protein[18]. MET exon 14 skipping mutations act as oncogenic drivers in lung cancer mutually exclusive to activating mutations in EGFR and KRAS and other oncogenic fusions such as ALK and ROS1[17,19,20]. MET is amplified in 2-5% of ovarian cancer, esophageal adenocarcinoma, stomach adenocarcinoma, glioblastoma, and lung adenocarcinoma[14,21,22]. Recurrent MET fusions, although infrequent, are observed in adult and pediatric glioblastoma, papillary renal cell carcinoma, lung cancer, liver cancer, thyroid cancer, and melanoma[23,24,25]. MET alterations are believed to be enriched in late-stage cancers where they drive tumor progression and metastasis[26,27,28].

Potential relevance: In 2020, the FDA granted accelerated approval to capmatinib[29] for NSCLC harboring MET exon 14 skipping positive as detected by an FDA-approved test. The kinase inhibitor, tepotinib[30], is also approved (2021) for MET exon 14 skipping mutations in NSCLC. MET exon 14 skipping mutations confer sensitivity to approved kinase inhibitors including crizotinib (2011), which is recommended for MET amplifications and exon 14 skipping mutations[17,19,20,31]. The FDA also granted breakthrough therapy designation (2018) to crizotinib for metastatic non-small cell lung cancer (NSCLC) with MET exon 14 alterations with disease progression on or after platinum-based chemotherapy[32]. Conversely, amplification of MET has been observed to mediate resistance to EGFR tyrosine kinase inhibitors (TKIs)[33,34,35,36,37]. However, the FDA has granted Fast Track designation (2021) to the MET/CSF1R/SRC small molecule inhibitor, TPX-0022[38], for MET amplified advanced or metastatic gastric cancer, including gastroesophageal junction adenocarcinoma (GEJ) after prior chemotherapy. In a phase II trial testing the MET inhibitor savolitinib, patients with advanced PRCC exhibited median progression free survival (PFS) of 6.2 and 1.4 months for MET-driven and MET-independent PRCC, respectively[39].

Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ✖ No evidence

MET exon 14 skipping

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
capmatinib	●	●	✖	●	● (III)
tepotinib	●	●	✖	●	● (II)
crizotinib	✖	●	✖	●	● (II)
savolitinib	✖	✖	✖	✖	● (III)
bozitinib	✖	✖	✖	✖	● (II)
cabozantinib	✖	✖	✖	✖	● (II)
datopotamab deruxtecan	✖	✖	✖	✖	● (II)
sintilimab	✖	✖	✖	✖	● (II)
TQ-B3139	✖	✖	✖	✖	● (II)
elzovantinib	✖	✖	✖	✖	● (I/II)
EMB01	✖	✖	✖	✖	● (I/II)
glumetinib	✖	✖	✖	✖	● (I/II)
LM-061	✖	✖	✖	✖	● (I/II)
MCLA-129	✖	✖	✖	✖	● (I/II)
REGN-5093	✖	✖	✖	✖	● (I/II)
amivantamab	✖	✖	✖	✖	● (I)
BPI-9016M	✖	✖	✖	✖	● (I)
HLX55	✖	✖	✖	✖	● (I)
PF-07265807	✖	✖	✖	✖	● (I)
RC-108	✖	✖	✖	✖	● (I)
SPH3348, osimertinib	✖	✖	✖	✖	● (I)
ST-1898	✖	✖	✖	✖	● (I)

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Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
itacitinib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Relevant Therapy Details

Current FDA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types

FDA information is current as of 2022-02-16. For the most up-to-date information, search www.fda.gov.

MET exon 14 skipping

● capmatinib

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2022-01-21 **Variant class:** MET exon 14 skipping

Indications and usage:

TABRECTA™ is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

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

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213591s002lbl.pdf

● tepotinib

Cancer type: Non-Small Cell Lung Cancer **Label as of:** 2021-02-03 **Variant class:** MET exon 14 skipping

Indications and usage:

TEPMETKO® is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

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

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf

Current NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types

NCCN information is current as of 2022-02-01. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

MET exon 14 skipping

● capmatinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Brain Metastases (Line of therapy not specified)

Reference: NCCN Guidelines® - NCCN-Central Nervous System Cancers [Version 2.2021]

● capmatinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (First-line therapy); Preferred intervention
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (Subsequent therapy); Preferred intervention
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic, Progression (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 1.2022]

● crizotinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (First-line therapy); Useful in certain circumstances
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (Subsequent therapy)
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic, Progression (Subsequent therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 1.2022]

MET exon 14 skipping (continued)

tepotinib

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (First-line therapy); Preferred intervention
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic (Subsequent therapy); Preferred intervention
- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic, Progression (Subsequent therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 1.2022]

Current ESMO Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types

ESMO information is current as of 2022-02-01. For the most up-to-date information, search www.esmo.org.

MET exon 14 skipping

● capmatinib

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

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):
- (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

● crizotinib

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

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):
- (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

● tepotinib

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

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):
- (Line of therapy not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-Metastatic Non-Small-Cell Lung Cancer [Online Guideline (15SEP2020 - https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer); Ann Oncol (2018) 29 (suppl 4): iv192–iv237.]

Clinical Trials in Taiwan region:

Clinical Trials Summary

MET exon 14 skipping

NCT ID	Title	Phase
NCT04427072	A Phase III, Randomized, Controlled, Open-label, Multicenter, Global Study of Capmatinib Versus SoC Docetaxel Chemotherapy in Previously Treated Patients With EGFR wt, ALK Negative, Locally Advanced or Metastatic (Stage IIIB/IIIC or IV) NSCLC Harboring MET Exon 14 Skipping Mutation (METdeltaex14).	III
NCT04923945	A Multi-center, Open-label, Phase IIIb Confirmatory Clinical Trial to Evaluate the Efficacy, Safety and Tolerability of Savolitinib in Treating Locally Advanced or Metastatic NSCLC Patients With MET Exon 14mutations	III
NCT04258033	A Phase II, Open-label, Multicenter and Multi-cohorts Study to Evaluate the Efficacy and Safety of PLB1001 in Advanced Non-small Cell Lung Cancer With c-Met Dysregulation	II
NCT03911193	Phase II Single Arm Study With CABozantinib in Non-Small Cell Lung Cancer Patients With MET Deregulation	II
NCT04677595	A Phase II, Multicenter, Two-cohort Study of Oral MET Inhibitor Capmatinib in Chinese Adult Patients With EGFR Wild-type (wt), ALK Rearrangement Negative, MET Exon 14 Skipping Mutations, Advanced Non-small Cell Lung Cancer (NSCLC) Who Are Treatment Naive or Failed One or Two Prior Lines of Systemic Therapy	II
NCT04926831	Phase II Trial of Neoadjuvant and Adjuvant Capmatinib in Participants With Stages IB-IIIA, N2 and Selected IIIB (T3N2 or T4N2) NSCLC With MET Exon 14 Skipping Mutation or High MET Amplification (Geometry-N)	II
NCT04084717	Phase II Study of Crizotinib for ROS1 and MET Activated Lung Cancer (CROME)	II
NCT04484142	Phase II, Single-arm, Open-label Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations and Progressed On or After Applicable Targeted Therapy and Platinum Based Chemotherapy (TROPION-Lung05)	II
NCT03574402	An Open-label, Multi-center, Phase II Umbrella Study to Assess Efficacy of Targeted Therapy or Immunotherapy Directed by Next Generation Sequencing (NGS) in Chinese Patients With Advanced NSCLC (TRUMP)	II
NCT04647838	A Phase II Study of Tepotinib in Patients With Solid Cancers Harboring c-MET Amplification or Exon 14 Mutation Who Progressed After Standard Treatment for Advanced/Metastatic Disease	II
NCT03175224	Phase I/II Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects With Non-Small Cell Lung Cancer With c-Met EXON 14 Skip Mutations and c-Met Dysregulation Advanced Solid Tumors.	I/II
NCT03993873	A Phase I, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0022, a Novel MET/CSF1R/SRC Inhibitor, in Patients With Advanced Solid Tumors Harboring Genetic Alterations in MET.	I/II
NCT04270591	A Phase Ib/II, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of Glumetinib (SCC244), a Selective MET Inhibitor in Patients With Advanced Non-Small Cell Lung Cancer Harboring MET-alterations	I/II
NCT04882176	Phase I/II Clinical Study Of The Safety, Tolerability, Pharmacokinetic Characteristics And Preliminary Efficacy Of The Kinase Inhibitor LM-061 Tablet In Patients With Advanced Solid Tumors	I/II
NCT04930432	A Phase I/II Study of MCLA-129, a Human Anti-EGFR and Anti-c-Met Bispecific Antibody, in Patients With Advanced NSCLC and Other Solid Tumors, Evaluating Safety, Pharmacokinetic Characteristics and Antitumor Activity	I/II
NCT04077099	A Phase I/II Study of REGN5093 in Patients With MET-Altered Advanced Non-Small Cell Lung Cancer	I/II

Clinical Trials Summary (continued)

MET exon 14 skipping (continued)

NCT ID	Title	Phase
NCT02609776	A Phase I, First-in-Human, Open-Label, Dose Escalation Study of JNJ-61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects With Advanced Non-Small Cell Lung Cancer	I
NCT02929290	Safety, Efficacy and Pharmacokinetic of BPI-9016M in Patients With c-Met- Dysregulated Advanced NSCLC: A Phase Ib Study,Open-label,Dose-expansion Study	I
NCT03466268	A Phase I Clinical Study to Assess the Safety, Pharmacokinetics and Antitumor Activity of SCC244 in Patients with Advanced Solid Tumors	I
NCT04169178	A Phase I Dose Finding/Expansion Study of HLX55, A Monoclonal Antibody Targeting Tyrosine-Protein Kinase MET (C-MET) in Patients With Advanced Solide Tumors Refactory to Standard Therapy	I
NCT04458259	A PHASE I, OPEN-LABEL, MULTI-CENTER, DOSE-FINDING, PHARMACOKINETIC, SAFETY AND TOLERABILITY STUDY OF PF-07265807 IN PARTICIPANTS WITH SELECTED ADVANCED OR METASTATIC SOLID TUMOR MALIGNANCIES	I
No NCT ID	Phase I Clinical Trial of the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of ST-1898 Tablets in Patients with Advanced Solid Tumors	I
NCT04617314	A Phase I Study to Evaluate the Safety, Pharmacokinetics, and Effect of RC108-ADC For Injection in Subjects With c-Met Positive Advanced Malignant Solid Tumors	I
NCT04398940	A Single-arm, Multicenter Study to Evaluate the Efficacy and Safety of TQ-B3139 in Subjects With MET-Altered Advanced Non-small Cell Lung Cancer	II
NCT03797391	First-in-human, Phase I/II, Multicenter, Open-Label Study of EMB-01 in Patients With Advanced/ Metastatic Solid Tumors	I/II
NCT02693535	Targeted Agent and Profiling Utilization Registry (TAPUR) Study.	II
NCT04423185	Platform Study of Genotyping Guided Precision Medicine for Rare Tumors in China	II
NCT03457532	A Multi-center, Open-label, Dose Escalation and Dose Extension Phase I Study to Evaluate the Safety , Tolerability, Pharmacokinetics and Preliminary Efficacy of SCC244 in Advanced Solid Tumors Patients With c-MET Alteration	I
NCT05088070	Phase I Clinical Study of SPH3348 Tablets, a c-Met Inhibitor, in Patients With Advanced Solid Tumors With c-Met Abnormalities	I
NCT03297606	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial	II

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NCT ID	Title	Phase
NCT04591431	The Rome Trial From Histology to Target: the Road to Personalize Target Therapy and Immunotherapy	II

Alerts Informed By Public Data Sources

Current FDA Information

Contraindicated Not recommended Resistance Breakthrough Fast Track

FDA information is current as of 2022-02-16. For the most up-to-date information, search www.fda.gov.

MET exon 14 skipping

crizotinib

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

Supporting Statement:
The FDA has granted Breakthrough Therapy Designation to the tyrosine kinase inhibitor, crizotinib, for metastatic non-small cell lung cancer (NSCLC) with MET exon 14 alterations with disease progression on or after platinum-based chemotherapy.

Reference:

https://www.pfizer.com/news/press-release/press-release-detail/pfizer_s_xalkori_crizotinib_receives_fda_breakthrough_therapy_designation_in_two_new_indications-0

Signatures

Testing Personnel:

Laboratory Supervisor:

Pathologist:

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