Clinical Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type Advanced Non-small Cell Lung Cancer

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Main Information

Primary registry identifying number
LBCTR2019121368

Protocol number
CINC280A2201

MOH registration number
4331/ص

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
This study already started before LBCTR registry and still ongoing

Date of registration in national regulatory agency
15/05/2015

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharma Services Inc.

Date of registration in primary registry
07/01/2020

Date of registration in national regulatory agency
15/05/2015

Public title
Clinical Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type Advanced Non-small Cell Lung Cancer

Acronym

Scientific title
A Phase II, Multicenter Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type (wt), Advanced Non-small Cell Lung Cancer (NSCLC)

Acronym

Brief summary of the study: English
A phase II study to evaluate antitumor activity of oral cMET inhibitor INC280 in adult patients with EGFR wild-type, advanced non-small cell lung cancer (NSCLC) as measured by overall response rate (ORR). The study will also evaluate safety and pharmacokinetics of INC280.

Brief summary of the study: Arabic
دراسة مرحلة ثانية متعددة المراكز لمثبّط cMET الفموي INC280 لدى المرضى البالغين المصابين بسرطان الرئة غير ذي الخلايا الصغيرة المتقدّم من النوع الحاد EGFR

Health conditions/problem studied: Specify
advanced non-small cell lung cancer (NSCLC)

Interventions: Specify
INC280 (capmatinib)

Key inclusion and exclusion criteria: Inclusion criteria
Inclusion Criteria:
•Stage IIIB or IV NSCLC (any histology) at the time of study entry

•Histologically or cytologically confirmed diagnosis of NSCLC that is:

1.EGFR wt as per patient standard of care by a validated test
2.AND ALK-negative rearrangement as part of the patient standard of care by a validated test

3.AND (by central assessment) either:
Cohort 1: Pre-treated patients with cMET GCN ≥ 6 or
Cohort 2: Pre-treated patients with cMET GCN ≥4 and < 6, or
Cohort 3: Pre-treated patients with cMET GCN < 4, or
Cohort 4: Pre-treated patients with cMET mutations regardless of cMET GCN, or
Cohort 5: Treatment-naïve patients with cMET dysregulation, or
Cohort 6: Pre-treated patients with either cMET GCN ≥ 10 without cMET mutations or cMET mutations regardless of cMET GCN, or
Cohort 7: Treatment-naïve patients with cMET mutations regardless of cMET GCN

•To be eligible for Cohorts 1-4, patients must have failed one or two prior lines of systemic therapy for advanced/metastatic disease
•To be eligible for Cohort 6, patients must have failed one prior line of systemic therapy for advanced/metastatic disease
•To be eligible for Cohort 5 and Cohort 7, patients must not have received any systemic therapy for advanced/metastatic disease
•At least one measurable lesion as defined by RECIST 1.1
•Patients must have recovered from all toxicities related to prior anticancer therapies to grade ≤ 1 (CTCAE v 4.03). Patients with any grade of alopecia are allowed to enter the study.
•Patients must have adequate organ function
•ECOG performance status (PS) of 0 or 1 Details and other protocol-defined inclusion criteria may apply

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:
•Prior treatment with crizotinib, or any other cMET or HGF inhibitor
•Patients with characterized EGFR mutations that predict sensitivity to EGFR therapy, including, but not limited to exon 19 deletions and exon 21 mutations
•Patients with characterized ALK-positive rearrangement
•Clinically significant, uncontrolled heart diseases.

•Patients receiving treatment with medications that cannot be discontinued at least 1 week prior to first INC280 treatment and for the duration of the study:
◦Strong inducers of CYP3A4

•Impairment of GI function or GI disease that may significantly alter the absorption of INC280
•Patients receiving treatment with any enzyme-inducing anticonvulsant
•Applicable to Cohorts 1-4 and Cohort 6 only: Previous anti-cancer and investigational agents within 4 weeks or ≤ 5 x half-life of the agent (whichever is longer) before first dose
•Pregnant or nursing women
•Women of child-bearing potential, unless they are using highly effective methods of contraception
•Sexually active males unless they use a condom during intercourse
•Presence or history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis

Other protocol-defined exclusion criteria may apply

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

2

Study design: Purpose

Study design: Specify purpose

Treatment

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

INC280 (capmatinib)

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

adenosine triphosphate (ATP) competitive, reversible inhibitor of the c-MET receptor tyrosine kinase

Therapeutic indication

Adult male and female patients with EGFR wt (for exon 19 deletions and exon 21 L858R substitution mutations), ALK-negative rearrangement, advanced (stage IIIB or IV) NSCLC who have received one or two prior lines of systemic therapy for advanced/metastatic disease.

Therapeutic benefit

Overall Response Rate (ORR)

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Samples shipped to central laboratory.

Target sample size

3

Actual enrollment target size

3

Date of first enrollment: Type
Actual

Date of first enrollment: Date
20/04/2016

Date of study closure: Type
Actual

Date of study closure: Date
25/12/2020

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
15/09/2020

IPD sharing statement plan
No

IPD sharing statement description
Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL
https://clinicaltrials.gov/ct2/show/record/NCT02414139?cond=Lung+Cancer&cntry=LB&draw=2

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical Trials .gov	NCT02414139

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Fadi Farhat	Saida	Lebanon	03-753155	drfadi.trials@gmail.com	Hammoud Hospital University Medical Center
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Public	Arafat Tfayli	Beirut	Lebanon	71-194294	Arafat.tfayli@aub.edu.lb	American University Of Beirut Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Fadi Farhat	Hematology- Oncology	Approved
American University of Beirut Medical Center	Arafat Tfayli	Hematology- Oncology	Approved
Hotel Dieu De France	Joseph Kattan	Hematology- Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	14/09/2015	Fuad Ziyadeh	fz05@aub.edu.lb	961 (0) 1 350 000 ext:5445
Hotel Dieu de France	17/04/2015	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335
Hammoud Hospital University Medical Center	02/06/2017	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 1160

Countries of Recruitment

Name
Lebanon
Argentina
Austria
Brazil
Canada
China
France
Germany
Italy
Japan
Mexico
Netherlands
Norway
Turkey
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
advanced non-small cell lung cancer (NSCLC)	Bronchus or lung, unspecified (C34.9)	advanced non-small cell lung cancer (NSCLC)

Interventions

Intervention	Description	Keyword
Lab tests, ECG, Physical Exam , ICF	Lab tests, ECG, Physical Exam , ICF	Lab tests, ECG, Physical Exam , ICF

Primary Outcomes

Name	Time Points	Measure
Overall Response Rate (ORR)	18 weeks	18 weeks

Key Secondary Outcomes

Name	Time Points	Measure
Duration of Response (DOR)	18 weeks	18 weeks
Progression-free Survival	18 weeks	18 weeks

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files