



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

13/08/2025 15:00:32

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

29/02/2024

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

لدى المرضى البالغين المصابين بسرطان الرئة غير ذي الخلايا الصغيرة INC280 القموي cMET دراسة مرحلة ثانية متعددة المراكز لمقبط EGFR المتقدم من النوع الحاد

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 $\leq 5 \times$ 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 | Study design: Specify assignment | |
| Single | N/A | |
| IMP has market authorization | IMP has market authorization: Specify | |
| No | | |
| Name of IMP | Year of authorization | Month of authorization |
| INC280 (capmatinib) | | |
| 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 | Study model: Explain model | |
| N/A | N/A | |
| Study model: Specify model | | |
| N/A | | |
| Time perspective | Time perspective: Explain time perspective | |
| N/A | N/A | |
| Time perspective: Specify perspective | | |
| N/A | | |
| Target follow-up duration | Target follow-up duration: Unit | |
| | | |
| Number of groups/cohorts | | |
| | | |
| Biospecimen retention | Biospecimen description | |
| Samples with DNA** | Samples shipped to central laboratory. | |
| Target sample size | Actual enrollment target size | |
| 3 | 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 02/03/2023 |
| Recruitment status Complete | Recruitment status: Specify |
| Date of completion 12/02/2020 | |
| 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 |
|--------------|-------------------|------------|---------|--------------------|-------------------------------|--|
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| Public | Joseph Kattan | Beirut | Lebanon | 03-635913 | jkattan62@hotmail.com | Hotel Dieu De France |
| 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 | Sami Richa | cue@usj.edu.lb | 961421229 |
| 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