ASCEND 8-Pharmacokinetic and Safety Study of Lower Doses of Ceritinib Taken With a Low-fat Meal Versus 750 mg of Ceritinib in the Fasted State in Adult Patients With (ALK-positive) Metastatic Non-small Cell Lung Cancer (NSCLC)

11/04/2025 07:57:04

Main Information

Primary registry identifying number
LBCTR2019121369

Protocol number
CLDK378A2112

MOH registration number
9537/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 was previously submitted before LBCTR and still ongoing

Date of registration in national regulatory agency
22/10/2015

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
22/10/2015

Public title
ASCEND 8-Pharmacokinetic and Safety Study of Lower Doses of Ceritinib Taken With a Low-fat Meal Versus 750 mg of Ceritinib in the Fasted State in Adult Patients With (ALK-positive) Metastatic Non-small Cell Lung Cancer (NSCLC)

Acronym

Scientific title
A Multi-center, Randomized Open Label Study to Assess the Systemic Exposure, Effiacy, and Safety of 450 mg Ceritinib Taken With a Low-fat Meal and 600 mg Ceritinib Taken With a Low-fat Meal as Compared With That of 750 mg Ceritinib Taken in the Fasted State in Adult Patients With ALK Rearranged (ALK-positive) Metastatic Non-small Cell Lung Cancer (NSCLC)

Acronym

Brief summary of the study: English
A Phase I study to assess the systemic exposure, effiacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC)

Brief summary of the study: Arabic
ملغ المأخوذ مع وجبة قليلة الدهون وفعاليّته450دراسة جزافيّة متعددة المراكز مفتوحة اللصاقة لتقييم التعرّض الجهازي لدواء سيريتينيب ملغ المأخوذ على معدة فارغة لدى مرضى750 ملغ المأخوذ مع وجبة قليلة الدهون مقارنة بدواء سيريتينيب 600وسلامته ودواء سيريتينيب بالغين مصابين بسرطان الرئة النقيلي غير ذي الخلايا الصغيرة، كيناز الورم اللمفي الكشمي المعاد ترتيبه (كيناز الورم اللمفي الكشمي الإيجابي)

Health conditions/problem studied: Specify

Metastatic non-small cell lung cancer (NSCLC)

Interventions: Specify

Drug: ceritinib
•Experimental: ceritinib 450 mg with a low-fat meal
Intervention: Drug: ceritinib

•Experimental: ceritinib 600 mg with a low-fat meal
Intervention: Drug: ceritinib

•Active Comparator: ceritinib 750 mg on an empty stomach
Intervention: Drug: ceritinib

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion:
1.Histologically or cytologically confirmed diagnosis of stage IIIB (and is not a candidate for definitive multimodality therapy) or IV ALK-positive NSCLC.
2.Patients may have received one prior treatment regimen with crizotinib (all other ALK inhibitors are excluded).
3.Patients may have received prior chemotherapy, biologic therapy, or other investigational agents. ALK inhibitors other than crizotinib are excluded.
4.Patient has a World Health Organization (WHO) performance status 0-2.

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:
1.Prior treatment with an ALK inhibitor other than crizotinib.
2.History of carcinomatous meningitis.
3.Presence or history of a malignant disease other than an ALK-positive advanced tumor that has been diagnosed and/or required therapy within the past 3 years.

5. Clinically significant, uncontrolled heart disease and/or recent cardiac event (within 6 months) 6. Patient has history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis (i.e., affecting activities of daily living or requiring therapeutic intervention).

7. Patient has other severe, acute, or chronic medical conditions 8. Patient is currently receiving treatment with warfarin sodium (Coumadin®) or any other coumarin-derivative anticoagulants.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Pharmacokinetic

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Dose comparison

Study phase

1

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

No

Name of IMP

LDK378 (ceritinib)

Year of authorization

Month of authorization

Type of IMP

Cell therapy

Pharmaceutical class

5-Chloro-2-N-{5-methyl-4-(piperidin-4-yl)-2-[(propan-2-yl)oxy]phenyl}-4-N-[2-(propane-2-sulfonyl) phenyl]pyrimidine-2,4-diamine

Therapeutic indication

The study population will consist of previously treated and treatment-naive adult patients with metastatic ALK-positive NSCLC.

Therapeutic benefit

Overall Response Rate (ORR) and Duration of Response (DOR)

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 are being shipped to a central Lab

Target sample size

5

Actual enrollment target size

5

Date of first enrollment: Type

Actual

Date of first enrollment: Date

10/02/2016

Date of study closure: Type

Actual

Date of study closure: Date

05/05/2020

Recruitment status
Complete

Recruitment status: Specify

Date of completion
23/10/2017

IPD sharing statement plan
No

IPD sharing statement description
not provided

Additional data URL
https://clinicaltrials.gov/ct2/show/record/NCT02299505?term=ldk378&cntry=LB&draw=1&rank=4

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical trials.gov	NCT02299505

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	Marwan Ghosn	Beirut	Lebanon	03-226842	marwanghosnmd@yahoo.com	Hotel Dieu De France
Scientific	Hind Khairallah	Sinelfil	Lebanon	+961 1512002Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Fadi El Karak	Beirut	Lebanon	03-061621	felkarak@yahoo.com	Bellevue Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Marwan Ghosn	Hematology oncology	Approved
Bellevue Medical Center	Fadi El Karak	Hematology oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	25/09/2015	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Bellevue Medical Center	10/06/2016	Ghassan Maalouf	gmaalouf@bmc.com.lb	+961 (0) 1 682666 ext 7600

Countries of Recruitment

Name
Lebanon
Australia
Austria
Belgium
Brazil
Bulgaria
Canada
Colombia
Czech Republic
Germany
Greece
India
Italy
Malaysia
Netherlands
Turkey
United Kingdom
United States of America

Health Conditions or Problems Studied

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

Interventions

Intervention	Description	Keyword
ICF, Lab tests, Vital signs , radiology, ECG	ICF, Lab tests, Vital signs , radiology, ECG	ICF, Lab tests, Vital signs , radiology, ECG

Primary Outcomes

Name	Time Points	Measure
Plasma concentration of ceritinib	Day 22	Day 22

Key Secondary Outcomes

Name	Time Points	Measure
Safety profile	12 weeks	12 weeks
Plasma concentration of ceritinib	Day 1	Day 1
•Duration of response (DOR)	every 6 weeks	every 6 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