



# 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)

22/11/2024 04:31:35

## 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

15/12/2020

### 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, Efficacy, 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, efficacy, 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 وفعاليتها 450 دراسة جزئية متعددة المراكز مفتوحة اللصاقة لتقييم التعرض الجهازى لدواء سيريتينيب ملغ المأخوذ على معدة فارغة لدى مرضى 750 ملغ المأخوذ مع وجبة قليلة الدهون مقارنة بدواء سيريتينيب 600 و سلامته ودواء سيريتينيب بالغين مصابين بسرطان الرئة النقلي 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**

01/07/2020

**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	Sinefil	Lebanon	+961 1512002E xt. 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**