



# ASCEND 5: LDK378 Versus Chemotherapy in ALK Rearranged (ALK Positive) Patients Previously Treated With Chemotherapy (Platinum Doublet) and Crizotinib

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## Main Information

### Primary registry identifying number

LBCTR2019121371

### Protocol number

CLDK378A2303

### MOH registration number

9878/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 ongoing study was submitted before initiation of LBCTR

### Date of registration in national regulatory agency

10/11/2014

### Primary sponsor

Novartis Pharmaceuticals

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

07/01/2020

### Date of registration in national regulatory agency

10/11/2014

### Public title

ASCEND 5: LDK378 Versus Chemotherapy in ALK Rearranged (ALK Positive) Patients Previously Treated With Chemotherapy (Platinum Doublet) and Crizotinib

### Acronym

### Scientific title

A Phase III, Multicenter, Randomized, Open-label Study of Oral LDK378 Versus Standard Chemotherapy in Adult Patients With ALK-rearranged (ALK-positive) Advanced Non-small Cell Lung Cancer Who Have Been Treated Previously With Chemotherapy (Platinum Doublet) and Crizotinib

### Acronym

### Brief summary of the study: English

The primary purpose of the study was to compare the antitumor activity of LDK378 vs. chemotherapy in patients previously treated with chemotherapy (platinum doublet) and crizotinib.

### Brief summary of the study: Arabic

عن طريق الفم مقابل المعالجة الكيميائية العادية لدى مرضى LDK378 دراسة مرحلة ثالثة متعددة المراكز وجراحية ومفتوحة التسمية لدواء البالغين مصابين بسرطان الرئة غير ذي الخلايا الصغيرة المتقدم، كيناز الورم اللمفي الكشمي المعاد ترتيبه (كيناز الورم اللمفي الكشمي الإيجابي) وخاضعين سابقاً للمعالجة الكيميائية (البلاتين المزدوج) وللكريزوتينيب

### Health conditions/problem studied: Specify

Advanced non-small cell lung cancer (NSCLC)

### Interventions: Specify

•Drug: Ceritinib

Ceritinib is the investigational treatment and is referred to as the investigational study drug and was provided as 150 mg hard gelatin capsules for oral use. The dose was 750 mg once daily.





•Drug: pemetrexed

Pemetrexed was one of the chemotherapy treatments. Pemetrexed, a reconstituted solution, was intravenously administered over 10 minutes at 500 mg/m<sup>2</sup> every 21 days.

•Drug: docetaxel

Docetaxel was one of the chemotherapy treatments. Docetaxel, a reconstituted solution, was intravenously administered over 1 hour, at 75 mg/m<sup>2</sup> every 21 days.

**Key inclusion and exclusion criteria: Inclusion criteria**

Inclusion Criteria:

- 1.Patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as assessed by the FDA approved Abbott FISH Test.
- 2.Patient has stage IIIB or IV diagnosis and must have received one or two prior regimens (including platinum- doublet) of cytotoxic chemotherapy for the treatment of locally advanced or metastatic NSCLC.
- 3.Patient has at least one measurable lesion as defined by RECIST 1.1. A previously irradiated site lesion may only be counted as a target lesion if there is clear sign of progression since the irradiation
- 4.Patients must have received previous treatment with crizotinib for the treatment of locally advanced or metastatic NSCLC.

**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:

- 1.Patient with known hypersensitivity to any of the excipients of LDK378 (microcrystalline cellulose, mannitol, crospovidone, colloidal silicon dioxide and magnesium stearate)
- 2.Patient with a history of severe hypersensitivity reaction to pemetrexed or docetaxel or any known excipients of these drugs.
- 3.Patient with symptomatic central nervous system (CNS) metastases who is neurologically unstable or has required increasing doses of steroids within the 2 weeks prior to screening to manage CNS symptoms.

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Safety

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Active

**Study phase**

3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Worldwide

**IMP has market authorization: Specify**

Argentina, Aruba, Australia, Austria, Belgium, Brunei, Canada, Chile, China, Costa Rica, Croatia, Curacao, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Germany, ...

**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**

This study will be conducted in adult male or female patients, with ALK-rearranged (as determined by the Abbott FISH test), advanced (Stage IIIB or IV) NSCLC, who have received previous treatment with cytotoxic chemotherapy (one or two prior regimens, including one platinum doublet) and crizotinib, and have demonstrated disease progression at study enrollment. No particular sequence of prior crizotinib and chemotherapy is required for enrollment, and either can comprise the last treatment received by the patient.

**Therapeutic benefit**

Progression Free Survival (PFS) and Overall Survival (OS)

**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**

None retained

**Biospecimen description**

NA

**Target sample size**

2

**Actual enrollment target size**

2

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

28/01/2015

**Date of study closure: Type**

Actual

**Date of study closure: Date**

31/12/2020

**Recruitment status**

Complete

**Recruitment status: Specify**

**Date of completion**

30/10/2015

**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](http://www.clinicalstudydatarequest.com)

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT01828112?term=ldk378&cond=Lung+Cancer&cntry=LB&draw=1&rank=2>

**Admin comments****Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT01828112

## Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

## 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	Sin elfil	Lebanon	+961 1512002E xt. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.



## 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

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	22/10/2014	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335

## Countries of Recruitment

Name
Lebanon
Belgium
France
Canada
Germany
Italy
Japan
Netherlands
Turkey
United Kingdom
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
ICF, physical assessment, ECG, radiology, PK sampling	ICF, physical assessment, ECG, radiology, PK sampling	ICF, physical assessment, ECG, radiology, PK sampling

## Primary Outcomes

Name	Time Points	Measure
Progression Free Survival (PFS)	24 months	24 months

## Key Secondary Outcomes

Name	Time Points	Measure
Overall Survival (OS)	18 months	18 months
Overall Response Rate (ORR) [	18 months	18 months
Patient Reported Outcomes (PRO)	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**