



# ASCEND 4: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

LBCTR2019121370

### Protocol number

CLDK378A2301

### MOH registration number

10117/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 already submitted prior to LBCTR initiation. This study is still ongoing.

### Date of registration in national regulatory agency

17/11/2014

### 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

17/11/2014

### Public title

ASCEND 4: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 بالغين غير LDK378 دراسة مرحلة ثالثة متعددة المراكز وعشوائية التوزيع لدواء معالجين سابقًا ومصابين بسرطان الرئة غير الحرشفي غير ذي الخلايا الصغيرة، كيناز الورم اللامي الكشمي المعاد ترتيبه (كيناز الورم اللامي IV أو IIIB الكشمي الإيجابي)، المرحلة

### Health conditions/problem studied: Specify

stage IIIB (not candidates for definitive multimodality therapy) or stage IV non-squamous 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.

•Experimental: Ceritinib

Patients in this arm received 750 mg of ceritinib.

Intervention: Drug: Ceritinib

•Active Comparator: Chemotherapy

Patients in this arm received chemotherapy of either pemetrexed or docetaxel as determined by BIRC.

Interventions: •Drug: pemetrexed

•Drug: docetaxel

**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**

**Study design: Specify assignment**



Parallel

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 previously untreated adult patients, with ALK-rearranged (ALK-positive; as determined by the Ventana IHC-based diagnostic test) stage IIIB (not candidates for definitive multimodality therapy) or stage IV non-squamous NSCLC.

**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**

3

**Actual enrollment target size**

3

**Date of first enrollment: Type**

**Date of first enrollment: Date**

<b>Actual</b>	11/07/2014
<b>Date of study closure: Type</b>	<b>Date of study closure: Date</b>
Actual	31/12/2020
<b>Recruitment status</b>	<b>Recruitment status: Specify</b>
Complete	
<b>Date of completion</b>	
30/06/2015	
<b>IPD sharing statement plan</b>	<b>IPD sharing statement description</b>
No	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 <a href="http://www.clinicalstudydatarequest.com">www.clinicalstudydatarequest.com</a>
<b>Additional data URL</b>	
<a href="https://clinicaltrials.gov/ct2/show/record/NCT01828112?term=ldk378&amp;cond=Lung+Cancer&amp;cntry=LB&amp;draw=1&amp;rank=2">https://clinicaltrials.gov/ct2/show/record/NCT01828112?term=ldk378&amp;cond=Lung+Cancer&amp;cntry=LB&amp;draw=1&amp;rank=2</a>	
<b>Admin comments</b>	
<b>Trial status</b>	
Approved	

Secondary Identifying Numbers	
Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT01828099

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	Sin elfil	Lebanon	+961 151200251 2002	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Fadi Farhat	Saida	Lebanon	03-753155	drfadi.trials@gmail.com	Hammoud Hospital

## 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
Hammoud Hospital	Fadi Farhat	Hematology Oncology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	01/07/2013	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335
Hammoud Hospital University Medical Center	11/06/2013	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 1160



## Countries of Recruitment

Name
Lebanon
Belgium
Canada
France
Germany
Ireland
Japan
Netherlands
Portugal
Spain
Switzerland
Turkey
United Kingdom
United States of America

## Health Conditions or Problems Studied

Condition	Code	Keyword
Lung Cancer	Bronchus or lung, unspecified (C34.9)	NSCLC

## Interventions

Intervention	Description	Keyword
Lab tests , ICF, ECOG, Vital signs, CT scan, Bone scan	Lab tests , ICF, ECOG, Vital signs, CT scan, Bone scan	Lab tests , ICF, ECOG, Vital signs, CT scan, Bone scan

## 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