



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

09/10/2020

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/m² 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/m² 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



Actual	11/07/2014
Date of study closure: Type	Date of study closure: Date
Actual	31/12/2020
Recruitment status	Recruitment status: Specify
Complete	
Date of completion	
30/06/2015	
IPD sharing statement plan	IPD sharing statement description
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 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	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