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
11/11/2021

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 الكيميائيّة العاديّة لدى مرضى بالغين غير LDK378 دراسة مرحلة ثالثة متعددة المراكز وعشوائيّة التوزيع لدواء معالجين سابقًا ومصابين بسرطان الرئة غير الحرشفي غير ذي الخلايا الصغيرة، كيناز الورم اللمفي الكشمي المعاد ترتيبه (كيناز الورم اللمفي الكشمي الإيجابي)، المرحلة IIIB أو IV

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

Actual

Date of study closure: Date

31/12/2020

Recruitment status

Complete

Recruitment status: Specify

Date of completion

30/06/2015

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

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 1512002512002	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	Sami Richa	cue@usj.edu.lb	961421229
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