



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

20/08/2025 05:55:14

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

13/08/2024

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 وجزائية ومفتوحة التسمية لدواء بالغين مصابين بسرطان الرئة غير ذي الخلايا الصغيرة المتقدم، كيناز الورم اللمفي الكشمي المعاد ترتيبه (كيناز الورم اللمفي الكشمي الإيجابي) وخاضعين سابقاً للمعالجة الكيميائية (البلاطين 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/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.

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

04/04/2023

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

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 | Sami Richa | cue@usj.edu.lb | 961421229 |

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