



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

16/05/2023

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 عشوائية التوزيع لدواء معالجين سابقاً ومصابين بسرطان الرئة غير الحرشفي غير ذي الخلايا الصغيرة، كيناز الورم اللمفي الكشمي المعاد ترتيبه (كيناز الورم اللمفي المرحلة IIIIB أو IV الكشمي الإيجابي)، المرحلة

Health conditions/problem studied: Specify

stage IIIIB (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 | 31/12/2023 |
| 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 | 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