# ASCEND 4:LDK378 Versus Chemotherapy in ALK Rearranged (ALK Positive) Patients Previously Treated With Chemotherapy (Platinum Doublet) and Crizotinib

**25/11/2024 17:08:52**

## 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**
26/12/2020

**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 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**