



# CLDK378A2X01B Roll over study in patients with ALK positive malignancies

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## Main Information

**Primary registry identifying number**

LBCTR2019010182

**Protocol number**

CLDK378A2X01B

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

**Primary sponsor**

Novartis Pharma Services Inc.

**Primary sponsor: Country of origin**

Novartis Pharmaceuticals

**Date of registration in primary registry**

16/01/2019

**Date of registration in national regulatory agency**

**Public title**

CLDK378A2X01B Roll over study in patients with ALK positive malignancies

**Acronym**

**Scientific title**

An open-label, multi-center, Phase IV, roll-over study in patients with ALK positive malignancies who have completed a prior Novartis-sponsored ceritinib (LDK378) study and are judged by the investigator to benefit from continued treatment with ceritinib

**Acronym**

**Brief summary of the study: English**

The rollover study will provide ceritinib to patients who are currently receiving treatment with ceritinib within a Novartis-sponsored study and in the opinion of the investigator, would benefit from continued treatment with ceritinib.

**Brief summary of the study: Arabic**

دراسة مرحلة رابعة مفتوحة اللصاقاة ومتعددة المراكز وتكميلية لدى مرضى مصابين بأورام خبيثة إيجابية كيناز الورم اللمفي الكشمي والذين وقرّر الباحث أنهم يستفيدون من مواصلة العلاج بسيريتينيب (LDK378) أنجزوا دراسة سابقة رعتها نوفارتيس حول سيريتينيب

**Health conditions/problem studied: Specify**

Non Small Cell Lung Cancer

**Interventions: Specify**

Drug : Ceritinib ( Zykadia ) capsules

**Key inclusion and exclusion criteria: Inclusion criteria**

- Patient is currently receiving treatment with ceritinib within a Novartis-sponsored study which has fulfilled the requirements for the primary objective and, in the opinion of the Investigator, would benefit from continued treatment.
- Patient has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements.
- Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures.



•Written informed consent obtained prior to enrolling in the roll-over study and receiving study medication. If consent cannot be expressed in writing, it must be formally documented and witnessed via an independent trusted witness.

**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**

- Patient has been permanently and prematurely discontinued from ceritinib study treatment in the parent study due to any reason.
- Patient currently has unresolved toxicities for which ceritinib dosing has been interrupted in the parent study.
- Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive serum hCG laboratory test.
- Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 3 months after stopping ceritinib treatment.
- Sexually active males unless they use a condom during intercourse while taking drug and for 3 months after stopping ceritinib and should not father a child for at least 3 months after the last dose of treatment.

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

N/A: Single arm study

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Active

**Study phase**

4

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Single

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Worldwide

**IMP has market authorization: Specify**

Albania, Argentina, Canada, United states, United Arab Emirates, Ukraine, Turkey, Switzerland, Saudi Arabia, Oman, Mexico , Malasia

**Name of IMP**

Zykadia

**Year of authorization**

**Month of authorization**

**Type of IMP**

Others

**Pharmaceutical class**

Ceritinib is a potent adenosine triphosphate (ATP)-competitive inhibitor of ALK kinase activity.

**Therapeutic indication**

patients with ALK positive malignancies Non small cell Lung Cancer

**Therapeutic benefit**

- To collect safety data: adverse events and serious adverse events
- To evaluate clinical benefit as assessed by the investigator

**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**

Samples without DNA

**Biospecimen description**

Local Lab tests to follow up on patients safety. No samples will be shipped outside Lebanon

**Target sample size**

1

**Actual enrollment target size****Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

11/02/2019

**Date of study closure: Type**

Anticipated

**Date of study closure: Date****Recruitment status**

Pending

**Recruitment status: Specify****Date of completion****IPD sharing statement plan**

No

**IPD sharing statement description**

Not decided

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/NCT02584933?term=CLDK378A2X01B&rank=1>

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ClinicalTrials.gov	NCT02584933
EUDRACT European Union Drug Regulating Authorities Clinical Trials	2015-001922-40

## 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	00961 1 613395	marwanghosnmd@yahoo.com	Hotel Dieu De France
Scientific	Hind Khairallah	Beirut	Lebanon	+961 1 512002 Ext. 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	Dr Marwan Ghson	Hematology Oncology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	05/12/2018	Marwan Ghosn	marwanghosnmd@yahoo.com	00961 1 613395



## Countries of Recruitment

Name
Lebanon
United States of America
Australia
Belgium
China
France
Germany
Italy
Russian Federation
Spain
Japan

## Health Conditions or Problems Studied

Condition	Code	Keyword
Non Small Cell Lung Cancer	Malignant neoplasm of bronchus and lung (C34)	NSCLC

## Interventions

Intervention	Description	Keyword
Reference Table 7.1 of protocol	Informed consent / patient history / drug administration / Lab tests	ICF/ IMP administration/ Lab tests

## Primary Outcomes

Name	Time Points	Measure
1.Number of Participants with Adverse Events as a Measure of Safety and Tolerability	[ Time Frame: Until no patients are left on study up to 5 years ]	up to 5 years



## Key Secondary Outcomes

Name	Time Points	Measure
To evaluate clinical benefit as assessed by	Proportion of patients with clinical benefit	Confirmation of clinical benefit of study treatment

## 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**