CLDK378A2X01B Roll over study in patients with ALK postive malignancies

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Main Information

Primary registry identifying number
LBCTR2019010182

Protocol number
CLDK378A2X01B

MOH registration number
53628/2018

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
27/12/2018

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
07/01/2020

Date of registration in national regulatory agency
27/12/2018

Public title
CLDK378A2X01B Roll over study in patients with ALK postive 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 اللصاقة ومتعددة المراكز وتكميليّة لدى مرضى مصابين بأورام خبيثة إيجابيّة كيناز الورم اللمفي الكشمي والذين أنجزوا دراسة سابقة رعتها نوفارتيس حول سيريتينيب (LDK378) وقرّر الباحث أنّهم يستفيدون من مواصلة العلاج بسيريتينيب

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 afer 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
1

Date of first enrollment: Type
Actual

Date of first enrollment: Date
26/03/2019

Date of study closure: Type
Actual

Date of study closure: Date
18/11/2021

Recruitment status
Complete

Recruitment status: Specify

Date of completion
26/03/2019

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 benfit of study treament

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