An Open Label, Multi-center Asciminib Roll-over Study to Assess Long-term Safety in Patients Who Have Completed a Novartis Sponsored Asciminib Study and Are Judged by the Investigator to Benefit From Continued Treatment

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Main Information

Primary registry identifying number
LBCTR2022055038

Protocol number
CABL001A2001B

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 Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
29/06/2022

Date of registration in national regulatory agency

Public title
An Open Label, Multi-center Asciminib Roll-over Study to Assess Long-term Safety in Patients Who Have Completed a Novartis Sponsored Asciminib Study and Are Judged by the Investigator to Benefit From Continued Treatment

Acronym
Asciminib Roll-over Study

Scientific title
An Open Label, Multi-center Asciminib Roll-over Study to Assess Long-term Safety in Patients Who Have Completed a Novartis Sponsored Asciminib Study and Are Judged by the Investigator to Benefit From Continued Treatment

Acronym

Brief summary of the study: English
This is a long term safety study for patients who have completed a Novartis sponsored asciminib study and are judged by the investigator to benefit from continued treatment

Brief summary of the study: Arabic
دراسة تمديد لدى مرضى أنجزوا دراسة حول أسكيمينيب برعاية نوفارتيس وبحسب تقدير الباحث يستفيدون من مواصلة العلاج

Health conditions/problem studied: Specify
Chronic Myelogenous Leukemia
Acute Lymphoblastic Leukemia

Interventions: Specify
- Drug: Asciminib single agent
Taken orally, twice daily (BID) or once daily (QD), in fasting state

Other Name: ABL001

- Drug: Asciminib
Taken orally, once daily, in the morning with low-fat meal or twice daily in fasting state
Other Name: ABL001

- Drug: Imatinib
Taken orally, once daily, in the morning with low-fat meal
Other Name: STI571

- Drug: Nilotinib
Taken orally, twice daily, on an empty stomach
Other Name: AMN107

- Drug: Bosutinib
Taken orally, once daily, with food

- Drug: Dasatinib
Taken orally, once daily in a fasted state, 1 or 2 hours before a meal
Other Name: Sprycel

Key inclusion and exclusion criteria: Inclusion criteria

1- Participant with PH+ CML or PH+ ALL currently receiving treatment with asciminib (single agent or in combination with imatinib, nilotinib or dasatinib), imatinib, nilotinib or bosutinib alone within a Novartis-sponsored study and, in the opinion of the Investigator, would benefit from continued treatment.
2- Participant has demonstrated compliance on the parent study protocol and is willing and able to comply with scheduled visits, treatment plans and any other study procedures.

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

1- Participant has been discontinued from parent study treatment.
2- Participant currently has unresolved toxicities reported as possibly related to study treatment in the parent study.
3- Participant's ongoing treatment is currently approved and reimbursed at country level.
4- Pregnant or nursing (lactating) women.
5- Women of child-bearing potential, unless they are using highly effective methods of contraception and willing to continue while taking study treatment.
6- Sexually active males receiving imatinib, nilotinib, bosutinib or dasatinib unwilling to follow the relevant contraception requirements in the local prescribing information.
7- Applicable only for participants on bosutinib treatment that switch to asciminib treatment at enrollment:
- Asymptomatic pancreatitis
- abnormal ECG
- any grade 3 or 4 toxicity not resolved to grade 2 or lower within 28 days before starting asciminib treatment

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

Non-randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Uncontrolled

Study phase

4

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization
No

IMP has market authorization: Specify

Name of IMP
Asciminib

Year of authorization

Month of authorization

Type of IMP
Cell therapy

Pharmaceutical class
orally bioavailable specific BCR-ABL inhibitor with a novel mechanism of action

Therapeutic indication
Chronic Myelogenous Leukemia
Acute Lymphoblastic Leukemia

Therapeutic benefit
increase OS & PFS

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
N/A

Target sample size
1

Actual enrollment target size

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
08/08/2022

Date of study closure: Type

Anticipated

Date of study closure: Date

29/05/2026

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

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/NCT04877522?term=CABL001A2001B&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT04877522

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Ali Bazarbachi	Beirut	Lebanon	+961 3 612434	bazarbac@aub.edu.lb	American University of Beirut Medical Center
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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut Medical Center	Ali Bazarbachi	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	03/05/2022	Fuad Ziyadeh	fz05@aub.edu.lb	+961 1 350000 ext:5445

Countries of Recruitment

Name
Lebanon
Germany
Italy
Japan
Republic of Korea
Mexico
Portugal
Russian Federation
Spain
Turkey
United Kingdom
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Chronic Myelogenous Leukemia	Leukaemia, unspecified (C95.9)	CML
Acute Lymphoblastic Leukemia	Leukaemia, unspecified (C95.9)	ALL

Interventions

Intervention	Description	Keyword
Consenting, IMP administration	Consenting, IMP administration	Consenting, IMP administration

Primary Outcomes

Name	Time Points	Measure
Number of participabts with adverse events (AEs) and serious adverse events (SAEs)	5 years	All AEs and SAEs will be tabulated and listed for participants in the Safety Set by treatment group. From day of first administration of study treatment to 30 days after the last study treatment.

Key Secondary Outcomes

Name	Time Points	Measure
Percentage of participants with clinical benefit as assessed by Investigator	5 years	Investigators' assessment of clinical benefit will collected through the Investigator confirming that the patient is still benefiting from treatment. This will be evaluated and tabulated for participants in the Safety Set by treatment group at each visit.

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