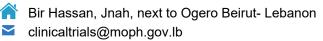
REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

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

11/08/2025 13:10:17

lain Information	
Primary registry identifying number	Protocol number
BCTR2022055038	CABL001A2001B
MOH registration number	
Study registered at the country of origin	Study registered at the country of origin: Specify
Yes	
Type of registration	Type of registration: Justify
Prospective	N/A
Date of registration in national regulatory agency	
Primary sponsor	Primary sponsor: Country of origin
Novartis Pharmaceuticals	Novartis Pharmaceuticals
Date of registration in primary registry	Date of registration in national regulatory agency
21/11/2023	
Public title	Acronym
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	Asciminib Roll-over Study
Scientific title	Acronym
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	
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	
انجزوا دراسة حول أسكيمينيب برعاية نوفارتيس وبحسب تقدير الباحث يستفيدون من مواصلة العلاج	دراسة تمديد لدى مرضى أ
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	



REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

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

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

Both

Key inclusion and exclusion criteria: Age minimum

18

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.

99

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	Trial scope: Specify scope
Safety	N/A
Study design: Allocation	Study design: Masking
Non-randomized controlled trial	Open (masking not used)
Study design: Control	Study phase
Uncontrolled	4
Study design: Purpose	Study design: Specify purpose
Treatment	N/A

REPUBLIC OF LEBANON Lebanon Clinical Trials Registry **MINISTRY OF PUBLIC HEALTH** Study design: Assignment Study design: Specify assignment Parallel N/A IMP has market authorization IMP has market authorization: Specify No Name of IMP Year of authorization Month of authorization Asciminib 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 Study model: Explain model N/A N/A Study model: Specify model N/A Time perspective: Explain time perspective **Time perspective** N/A N/A Time perspective: Specify perspective N/A Target follow-up duration Target follow-up duration: Unit Number of groups/cohorts **Biospecimen retention Biospecimen description** None retained N/A Target sample size Actual enrollment target size 1 1 Date of first enrollment: Date Date of first enrollment: Type

11/10/2022

Actual

 \sim

REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

Date of study closure: Type	Date of study closure: Date
Actual	29/10/2027
Recruitment status Complete	Recruitment status: Specify
Date of completion	
11/10/2022	
IPD sharing statement plan	IPD sharing statement description
Yes	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=CABL001A20	01B&draw=2&rank=1
Admin comments	

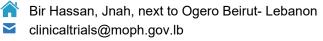
Trial status

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.e du.lb	American University of Beirut Medical Center
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 approva			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	