Roll-over Study to Allow Continued Access to Ribociclib

12/08/2025 18:20:23

Main Information

Primary registry identifying number
LBCTR2022095114

Protocol number
CLEE011A2412B

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
18/07/2024

Date of registration in national regulatory agency

Public title
Roll-over Study to Allow Continued Access to Ribociclib

Acronym

Scientific title
A Post-trial Access Roll-over Study to Allow Access to Ribociclib (LEE011) for Patients Who Are on Ribociclib Treatment in Novartis-sponsored Study

Acronym

Brief summary of the study: English
This is an open-label, multi-center, roll-over study to evaluate the long term safety of ribociclib in combination with other drugs in participants who are participating in a Novartis sponsored global study, that has fulfilled requirements for its primary objective(s), and who in the opinion of the Investigator, would benefit from continued treatment.

Brief summary of the study: Arabic
هذه دراسة تمديد مفتوحة التسمية ومتعددة المراكز لتقييم السلامة طويلة المدى لريبوسيكليب بالاشتراك مع أدوية أخرى في المشاركين الذين يشاركون في دراسة عالمية ترعاها شركة نوفارتيس، والتي أوفت بمتطلبات هدفها الأساسي (أهدافها)، ومن يعتقد طبيب الدراسة أنه سيستفيد من استمرار العلاج.

Health conditions/problem studied: Specify
Metastatic Breast Cancer

Interventions: Specify
Drug: Ribociclib (Participants continue ribociclib as was administered in their parent study)
Drug: Letrozole (Participants continue ribociclib in combination with letrozole as was administered in their parent study)
Drug: Anastrozole (Participants continue ribociclib in combination with anastrozole as was administered in their parent study)
Drug: Goserelin (Participants continue ribociclib in combination with goserelin as was administered in their parent study)
Drug: Tamoxifen (Participants continue ribociclib in combination with tamoxifen as was administered in their parent study)
Drug: Fulvestrant (All participants continue ribociclib in combination with fulvestrant as was administered in their parent study)

Key inclusion and exclusion criteria: Inclusion criteria

1. Currently participating in a Novartis sponsored global study (parent study), receiving treatment with ribociclib in combination with other drugs, and the parent study has fulfilled its primary objective(s)
2. Must have been receiving treatment with ribociclib for at least 6 cycles in the parent study
3. Currently has evidence of clinical benefit as determined by the Investigator

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. Permanent discontinuation of ribociclib in the parent study
2. Currently has unresolved toxicities for which ribociclib dosing has been interrupted in the parent study
3. Local access to commercially available ribociclib and reimbursed

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

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

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

US, EU, and other countries

Name of IMP

Ribociclib

Year of authorization

2017

Month of authorization

1

Type of IMP

Others

Pharmaceutical class

highly selective small molecule inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6)

Therapeutic indication

Metastatic Breast Cancer

Therapeutic benefit

continued treatment to participants who are currently receiving ribociclib

Study model

N/A

Study model: Explain model

Study model: Specify model
N/A

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
5

Actual enrollment target size
5

Date of first enrollment: Type
Actual

Date of first enrollment: Date
15/12/2022

Date of study closure: Type
Actual

Date of study closure: Date
16/02/2028

Recruitment status
Complete

Recruitment status: Specify

Date of completion
03/01/2023

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/NCT05161195?term=clee011A2412B&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT05161195

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Jawad Makarem	Al Chouf	Lebanon	+961 3 484288	jawad.Makarem@awmedicalvillage.org	Ain Wazein Medical Village
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l
Public	Nagi El Saghir	Beirut	Lebanon	+961 3 827955	ns23@aub.edu.lb	American University of Beirut Medical Center
Public	Joseph Kattan	Beirut	Lebanon	+961 3 635913	jkattan62@hotmail.com	Hotel Dieu de France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut Medical Center	Nagi El Saghir	Hematology Oncology	Approved
Ain Wazein Medical Village	Jawad Makarem	Hematology Oncology	Approved
Hotel Dieu de France	Joseph Kattan	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	05/09/2022	Rami Mahfouz	rm11@aub.edu.lb	+961 (0) 1 350 000 ext:5445
Ain w Zein Medical Village	25/08/2022	Hayat Kamaleddine	irb@awmedicalvillage.org	+961 (0) 5 509 001 ext 2014
Hotel Dieu de France	12/08/2022	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335

Countries of Recruitment

Name
Lebanon
Poland
Singapore
United States of America
Brazil
France
Greece
China
Italy
Japan
Republic of Korea
Mexico
Portugal
South Africa
Spain
Taiwan
Turkey

Health Conditions or Problems Studied

Condition	Code	Keyword
Metastatic Breast Cancer	Malignant neoplasm of breast (C50)	Metastatic Breast Cancer

Interventions

Intervention	Description	Keyword
ICF, IMP administration, local Labs	ICF, IMP administration, local Labs	ICF, IMP administration, local Labs

Primary Outcomes

Name	Time Points	Measure
Percentage of participants with treatment-emergent adverse events (AES)	From day of first dose of study medication to 30 days after last dose of study medication, up to 5 years	The percentage of participants with treatment-emergent adverse events will be summarized, including significant adverse events leading to discontinuation, and adverse events leading to dose adjustment

Key Secondary Outcomes

Name	Time Points	Measure
Clinical benefit rate	Up to 5 years	Percentage of participants with clinical benefit as assessed by the Investigator at scheduled study visits

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