



# Roll-over Study to Allow Continued Access to Ribociclib

25/11/2024 01:26:06

## 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**

01/08/2023

**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**

4

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

31/10/2022

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

16/02/2028

**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](http://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
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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 Kamaledine	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