



## Roll-over Study to Allow Continued Access to Ribociclib

13/08/2025 14:18:11

### 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**

28/07/2025

**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**

**Time perspective: Explain 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**

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](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**

No Numbers

**Sources of Monetary or Material Support**

No Sources

**Secondary Sponsors**

No Sponsors

**Contact for Public/Scientific Queries**

No Contacts

**Centers/Hospitals Involved in the Study**

No Centers/Hospitals

**Ethics Review**

No Reviews



## Countries of Recruitment

No Countries

## Health Conditions or Problems Studied

No Problems Studied

## Interventions

No Interventions

## Primary Outcomes

No Outcomes

## Key Secondary Outcomes

No Outcomes





## 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