Roll-over Study to Allow Continued Access to Ribociclib

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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
14/08/2025

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
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

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