# Roll-over Study to Allow Continued Access to Ribociclib

Last Update: Oct 15, 2024
A Post-trial Access Roll-over Study to Allow Access to Ribociclib (LEE011) for Patients Who Are on Ribociclib Treatment in Novartis-sponsored Study
ClinicalTrials.gov Identifier:
NCT05161195
Novartis Reference Number:CLEE011A2412B
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

## Study Description

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. The purpose of this study is to evaluate long-term safety and provide continued treatment to participants who are currently receiving ribociclib in combination with other drugs in a parent study, that has fulfilled requirements for its primary objective(s), and in the opinion of the Investigator, would benefit from continuing treatment at time of discontinuation from the parent study

Condition
Metastatic Breast Cancer
Phase
Phase4
Overall Status
Recruiting
Number of Participants
137
Start Date
Jul 07, 2022
Completion Date
Feb 16, 2028
Gender
All
Age(s)
18 Years - (Adult, Older Adult)

## Interventions

Drug

### Anastrozole

Participants continue ribociclib in combination with anastrozole as was administered in their parent study
Drug

### Fulvestrant

All participants continue ribociclib in combination with fulvestrant as was administered in their parent study
Drug

### Goserelin

Participants continue ribociclib in combination with goserelin as was administered in their parent study
Drug

### Letrozole

Participants continue ribociclib in combination with letrozole as was administered in their parent study
Drug

### Ribociclib

Participants continue ribociclib as was administered in their parent study
Drug

### Tamoxifen

Participants continue ribociclib in combination with tamoxifen as was administered in their parent study

## Eligibility Criteria

Key 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 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

Other protocol-defined inclusion/exclusion criteria may apply at the end

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