

# Ribociclib (LEE011) Rollover Study for Continued Access

Last Update: Apr 26, 2024

An Open-label, Multi-center Rollover Protocol for Patients Who Have Participated in a Novartis-sponsored Ribociclib (LEE011) Study and Are Continuing to Benefit From Ribociclib as Single Agent or in Combination With Other Investigational Treatments

ClinicalTrials.gov Identifier:

[NCT02934568](#)

Novartis Reference Number: CLEE011X2X01B

[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 study is to allow continued use of ribociclib (LEE011) as single agent or in combination with other investigational treatments in patients benefitting from treatment in an eligible Novartis-sponsored ribociclib (LEE011) study that has reached its primary objective(s) or has been halted for other reasons.

Condition

Continued Access to Study Treatment(s), Cancers With a Mass, Bulky Tumor, Nodule, Lump, Advanced Cancer, Advanced Solid Tumors, Advanced Solid Malignancies

Phase

Phase2

Overall Status

Recruiting

Number of Participants

50

Start Date

Dec 15, 2016

Completion Date

Sep 01, 2026

Gender

All

Age(s)

- 80 Years (Child, Adult, Older Adult)

## Interventions

Drug

**LEE011**

Single agent LEE011 or in combination with other treatments

## Eligibility Criteria

### Inclusion Criteria:

1. Patient is currently enrolled in an eligible Novartis-sponsored study and receiving ribociclib (LEE011) as single agent or in combination with other investigational treatment.
2. Patient is currently deriving clinical benefit from the study treatment, as determined by the investigator.

### Exclusion Criteria:

1. Patient has been permanently discontinued from ribociclib (LEE011) in the parent protocol for any reason.
2. Patients who do not meet parent protocol criteria to continue study treatment.

## Taiwan

### Novartis Investigative Site

Recruiting

Tainan,70403,Taiwan

## United States

### St Jude Childrens Research Hospital

Recruiting

Memphis,Tennessee,38105,United States

Giles Robinson

Kelley Booten

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## Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

### Novartis Pharmaceuticals

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Email:

### Novartis Pharmaceuticals

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**Source URL:** <https://prod1.novartis.com/clinicaltrials/study/nct02934568>

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