

# A Study of Ribociclib in Combination With Hormonal Therapy in HR+/HER2- Advanced or Metastatic Breast Cancer

Last Update: Jan 14, 2025

Real-World Evidence Study for the Safety and Effectiveness of Ribociclib in Combination With Hormonal Therapy in Patients With HR+/HER2- Advanced or Metastatic Breast Cancer in the Middle East Region

ClinicalTrials.gov Identifier:

[NCT06075758](#)

Novartis Reference Number: CLEE011AIC01

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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 a non-interventional, ambispective, observational cohort study describing the real-world safety data of approximately 550 Hormone receptor / Human epidermal growth factor receptor 2 (HR+/HER2-) advanced/metastatic breast cancer patients who have received ribociclib combined with hormonal therapy in pre- and postmenopausal women or men in Middle Eastern countries. The investigators will have a six-month recruitment period to include the eligible subjects as per the protocol selection criteria. Retrospective patients should have been on Ribociclib in combination with hormonal therapy for at least 18 months and stopped the medication before the patient's recruitment.

Ambispective patients should have initiated Ribociclib, in combination with hormonal therapy, for at least 12 months before the patient's recruitment date and are still on Ribociclib in combination with hormonal therapy at recruitment. These patients will be followed up till progression, death, Ribociclib discontinuation due to adverse events, or till a maximum period of 6 months, whichever comes first.

Data will be collected from patient electronic medical records in the sites chosen for patients who received Ribociclib, in combination with hormonal therapy, in the first or second-line setting available in the relevant institutions.

A total of 550 patients is planned for this study. The planned sample size should capture very common adverse events reported in previous studies as well as adverse events  $\geq 10\%$  occurring in grade 3 and grade 4 with precision  $\pm 2.5\%$ .

Condition

Breast Cancer

Overall Status

Recruiting

Number of Participants

550

Start Date

Mar 07, 2024

Completion Date

Jun 30, 2025

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

## Interventions

Other

### **ribociclib**

There is no treatment allocation for NIS trials, patients on administered ribociclib by prescription will be enrolled. Treatment plan represents the prescription.

## Eligibility Criteria

Inclusion Criteria:

1. Adult patients  $\geq 18$  years old at the time of receiving Ribociclib in combination with hormonal therapy.
2. Advanced /metastatic breast cancer
3. Estrogen-receptor-positive and/or progesterone receptor-positive breast cancer.
4. HER2-negative breast cancer.
5. Patients who received or currently receiving Ribociclib in combination with hormonal therapy in the first or second-line settings as per the routine practice.
6. For the ambispective part, patients should have initiated the Ribociclib, in combination with hormonal therapy, line of treatment at least 12 months before the patient's recruitment date and still continuing the drug at the baseline visit.
7. For retrospective patients only, the patients should have been on Ribociclib, in combination with hormonal therapy, for at least 18 months and stopped Ribociclib before the SIV date.enrollment
8. For ambispective part, patients agree to sign informed consent before their enrollment.

Exclusion Criteria:

1. Ribociclib-based treatment regimen beyond the second line.
2. Patients are currently participating in any other clinical trials.
3. Patient with a known hypersensitivity to any of the excipients of Ribociclib.
4. Patients who previously received any other CDK4/6 inhibitor .
5. For ambispective patients, patients who refuse to sign the informed consent

**Jordan**

**Novartis Investigative Site**

Recruiting

Amman,11941,Jordan

## **Oman**

### **Novartis Investigative Site**

Recruiting

Muscat,1331,Oman

## **Saudi Arabia**

### **Novartis Investigative Site**

Recruiting

Riyadh,11211,Saudi Arabia

## **United Arab Emirates**

### **Novartis Investigative Site**

Recruiting

Al Ain Abu Dhabi,United Arab Emirates

## **Worldwide Contacts**

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

### **Novartis Pharmaceuticals**

Phone: [+41613241111](tel:+41613241111)

Email: [novartis.email@novartis.com](mailto:novartis.email@novartis.com)

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