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 ≥ 10% occurring in grade 3 and grade 4 with precision ±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 ≥ 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 continuingcontinuing the drug at the baseline visit.
7. For retrospective patients only, the patients should have been on Ribocilib, 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

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Recruiting

Muscat,1331,Oman

Saudi Arabia

Novartis Investigative Site

Recruiting

Riyadh,11211,Saudi Arabia

United Arab Emirates

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Recruiting

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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.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06075758*

List of links present in page

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