Ribociclib Real-world Treatment Patterns and Clinical Outcomes Among Women With HR+/HER2- Advanced or Metastatic Breast Cancer in France

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Ribociclib Real-world Treatment Patterns and Clinical Outcomes Among Women With HR+/HER2- Advanced or Metastatic Breast Cancer in France: a National, Multicenter, Prospective, Non-interventional Study

ClinicalTrials.gov Identifier:

NCT05697146

Novartis Reference Number:CLEE011AFR01

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 a national, multicenter, prospective, non-interventional study in women with HR+/HER2- locally advanced or metastatic breast cancer (BC), for which a prior clinical decision to initiate ribociclib + endocrine therapy (ET) treatment according to the marketing authorization has been taken and was taken independent and prior to study participation decision. Included patients will be followed until the end of study, death or lost to follow-up even if ribociclib and ET are discontinued. The end of the study is defined as 3 years after the first visit of the last patient included (Last Patient First Visit \[LPFV\]). The total duration of the study will be 4 years and half (18 months of inclusion + 3 years of follow-up). Thus, a patient included at the beginning of the inclusion period will be followed for 4 years and half and a patient included at the end of the inclusion period will be followed for at least 3 years.

Condition

Breast Cancer

Overall Status

Recruiting

Number of Participants

482

Start Date

Dec 13, 2022

Completion Date

Jun 30, 2028

Gender

Female

Age(s)

18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

ribociclib + ET

There is no treatment allocation. Patients administered ribociclib + endocrine Therapy (ET) by prescription will be enrolled.

Eligibility Criteria

Inclusion Criteria:

Patients who meet all of the following criteria will be included in the RosaLEE study:

1. Adult women aged ≥ 18 years old at inclusion.
2. Pre-/Peri-/Postmenopausal women with locally advanced or metastatic HR+/HER2- BC.
3. Prior clinical decision (independent of study participation)to initiate ribociclib + ET treatment according to the marketing authorization.
4. Patients having given their non-objection to participate in the study.
5. Patients presenting with medical conditions to be treated with ribociclib + ET according to the summary of product characteristics.

Exclusion Criteria:

1. Patients for whom ribociclib + AI in treatment combination has been initiated before inclusion.
2. Patients for whom ribociclib + fulvestrant in treatment combination has been initiated before inclusion.
3. Patients for whom AI or fulvestrant in monotherapy has been initiated \> 28 days before inclusion.
4. Participation in any clinical study involving investigational therapy except for the Trans-RosaLEE study, conducted by the IPC.
5. Patient who is pregnant or has expressed desire for pregnancy during Ribociclib treatment.

France

Novartis Investigative Site

Recruiting

Paris,75970,France

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Recruiting

Cherbourg,50102,France

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Recruiting

Clermont-Ferrand,63011,France

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Besancon Cedex,25030,France

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Strasbourg cedex,67085,France

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Beziers,34535,France

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Vantoux,57070,France

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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/nct05697146*

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