A Non-interventional Study for Kisqali (Ribociclib) in Combination With an Aromatase Inhibitor for Adjuvant Treatment in Patients With HR+/HER2- Early Breast Cancer at High Risk of Recurrence

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A Non-interventional Study for Kisqali (Ribociclib) in Combination With an Aromatase Inhibitor for Adjuvant Treatment in Patients With HR+/HER2- Early Breast Cancer at High Risk of Recurrence to Evaluate Real-world Effectiveness, Safety Profile, Patient Compliance and Quality of Life

ClinicalTrials.gov Identifier:
NCT06830720

Novartis Reference Number:CLEE011O1DE01

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 non-interventional observational study evaluates the real-world effectiveness and safety profile of ribociclib in combination with an aromatase inhibitor for adjuvant treatment in patients with HR+/HER2- early breast cancer at high risk of recurrence, as well as patient compliance and quality of life. This non-interventional study aims to provide information on real-world effectiveness, safety and tolerability, management of adverse events, QoL and patient compliance of patients with HR+/HER2- early breast cancer at high risk of recurrence treated with ribociclib in combination with an non-steroidal aromatase inhibitor (NSAI) ± luteinizing hormone-releasing hormone (LHRH) with curative intent according to the German summary of product characteristics.

In order to put the results of patients treated with ribociclib into perspective, socio-economic data, data on QoL and patient compliance will also be collected from patients treated with abemaciclib + endocrine therapy (ET) ± LHRH as described in the respective local summary of product characteristics.

To understand reasons for treatment decision, and to analyze the clinical adoption of ribociclib + NSAI ± LHRH after EU approval over time, baseline data will be collected from cohorts of ribociclib + NSAI ± LHRH, abemaciclib + ET ± LHRH, and additionally from patients treated with ET monotherapy ± LHRH and analyzed cross-sectionally.

The study is planned to be rolled out into a broad set of German and optionally Austrian and Swiss breast centers and gynecological practices to describe clinical routine in a representative subset of the local healthcare eco-system. It will gather insights into the potential benefits and risks associated with ribociclib + NSAI ± LHRH in the adjuvant treatment of HR+/HER2- eBC patients at high risk of recurrence. This knowledge will inform about clinical decision-making and contribute to improved patient outcomes in routine practice.

Condition
Breast Neoplasms
Overall Status
Recruiting
Number of Participants
3250
Start Date
Feb 20, 2025
Completion Date
May 31, 2030
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

abemaciclib + ET ± LHRH

abemaciclib in combination with an endocrine therapy ± LHRH as described in the summary of product characteristics. This is an observational study. There is no treatment allocation. The decision to initiate treatment will be based solely on clinical judgement.
Drug

ET mono ± LHRH

endocrine monotherapy ± LHRH. This is an observational study. There is no treatment allocation. The decision to initiate treatment will be based solely on clinical judgement.
Drug

ribociclib + NSAI ± LHRH

ribociclib in combination with an aromatase inhibitor ± LHRH as described in the summary of product characteristics. This is an observational study. There is no treatment allocation. The decision to initiate treatment will be based solely on clinical judgement.

Eligibility Criteria

Inclusion Criteria:

* Histological diagnosis of HR+/HER2- early breast cancer with curative intent
* Patients must have an indication for a treatment with ribociclib + NSAI ± LHRH as described in the current SmPC/"Fachinformation" of ribociclib (to be included into the cohorts of ribociclib + NSAI ± LHRH and ET mono ± LHRH) or abemaciclib + ET ± LHRH as described in the current SmPC/"Fachinformation" of abemaciclib (to be included into the abemaciclib + ET ± LHRH cohort) in the adjuvant setting
* Before enrollment the treating physician has made the decision in accordance with the patient to treat the patient with either

* ribociclib + NSAI ± LHRH, or
* ET mono ± LHRH, or
* abemaciclib + ET ± LHRH and baseline is no longer than 2 weeks (14 days) prior to written informed consent for this study.

Baseline = for ribociclib + NSAI ± LHRH cohort: date of therapy start; for abemaciclib + ET ± LHRH cohort: date of therapy start; for ET mono ± LHRH cohort: 4 weeks after therapy start or 4 weeks after last non-endocrine based therapy, whichever is last.

* ≥18 years of age
* Written informed consent

Exclusion Criteria:

* Patient is currently under active treatment in any investigational trial or simultaneously participating in another Novartis-sponsored non-interventional study with ribociclib
* For ribociclib + NSAI ± LHRH cohort: ET pre-treatment is longer than 12 months, according to the current SmPC/"Fachinformation" of ribociclib; for abemaciclib + ET ± LHRH cohort: ET pre-treatment is longer than 12 weeks, according to the current SmPC/"Fachinformation" of abemaciclib

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