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A Prospective NIS to Evaluate the Clinical Outcomes of Risarg® (Ribociclib) Combined With Endocrine Therapy or Chemotherapy in Patients With HR+HER2 - aBC in Routine Clinical Practice in the Russia

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A Prospective NIS to Evaluate the Clinical Outcomes of Risarg® (Ribociclib) Combined With Endocrine Therapy or Chemotherapy in Patients With HR+HER2 - Advanced Breast Cancer in Routine Clinical Practice in the Russian Federation
ClinicalTrials.gov Identifier:
NCT06148506
Novartis Reference Number:CLEE011ARU04
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 is a prospective, non-interventional, primary data collection cohort study to evaluate the clinical outcomes of the combination of ribociclib + ET and combination chemotherapy in the real-life setting in Russia. This study is observational in nature; it does not impose a therapy, diagnostic/therapeutic interventions or a visit schedule. Patients with HR+HER2- advanced breast cancer that initiated treatment with ribociclib+ET or combination CT will be enrolled. Approximately, 188 patients will be included into each treatment cohort of the study across different study sites in the Russian Federation and will be assigned to one of the below treatment arms:

* Ribociclib arm: ribociclib (600 mg, 3 weeks on/1 week off)+ IA/FUL + goserilin for premenopausal patients (N = 188)
* Combination chemotherapy arm: physician's choice (N = 188) The study will consist of pre-index period, index date and follow up period. Retrospective data will be collected as such: Medical history, previous treatment for Breast cancer (neoad'uvant and ad'uvant if applicable).In this study an index date is defined as a start of ribociclib+ET or chemotherapy treatment. Post-index follow-up period is 24 months or Progressive disease.

Patients will attend the sites in accordance with routine clinical practice. It is assumed according to the clinical practice that visits will be conducted every 3-4 months. Patients will undergo standard procedures and tests according to clinical guidelines and physician's judgement. No additional diagnostic or monitoring procedures will be applied to the patients and epidemiological methods shall be used for the analysis of collected data. Available data from routine clinical management of the patients will be collected at patients' visits to the clinical site. Patients enrolled in the study will be followed up until death or study close whichever occurs first.

Condition
HR+HER2- Advanced Breast Cancer
Overall Status
Recruiting
Number of Participants
376
Start Date
Dec 28, 2023
Completion Date
Jun 30, 2027
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Combination chemotherapy

There is no treatment allocation. Participants with HR+HER2- aBC that initiated treatment with CT by prescription within the study enrollment timeline will be recruited.
Other

Ribociclib

There is no treatment allocation. Participants with HR+HER2- aBC that initiated treatment with ribociclib+ET by prescription within the study enrollment timeline will be recruited.

Eligibility Criteria

Inclusion Criteria:

1. Age ≥ 18 years at the moment of ribociclib+ET or CT initiation.
2. Female/Male gender.
3. Luminal A, Luminal B subtype.
4. Patients with ECOG performance status ≤ 2.
5. Confirmed diagnosis of locally advanced/metastatic not eligible to surgery HR+HER2- BC (de novo) for whom the treating physician took the decision to initiate treatment with ribociclib+IA/FUL or combination chemotherapy before entering the study in the first line of the treatment.
6. Multiple visceral metastases (including stable CNS mts).
7. Pre-/Pere /postmenopause.
8. Patient who initiated treatment with ribociclib+IA/FUL or combination chemotherapy no longer than 4 weeks (28 days) prior to written informed consent for this study.

Exclusion Criteria:

1. Patients with a life expectancy of less than 3 months per the investigator's judgment.

2. Patients participating in any interventional clinical trial that includes investigational or marketed products at the time of enrollment. (Patients participating in other investigator initiated research or NIS can be included as long as their standard of care is not altered by the study).
3. Patients on active treatment for malignancies other than aBC at the time of enrollment.
4. Patients who are unable to understand the nature of the study and are unwilling to sign an informed consent.
5. Patients with visceral crisis (according to ABC5 definition*) *Visceral crisis is defined as severe organ dysfunction, as assessed by signs and symptoms, laboratory studies and rapid progression of disease. Visceral crisis is not the mere presence of visceral metastases but implies important organ compromise leading to a clinical indication for the most rapidly efficacious therapy \[8\].

Examples: Liver visceral crisis: rapidly increasing bilirubin \>1.5 ULN in the absence of Gilbert's syndrome or biliary tract obstruction. Lung visceral crisis: rapidly increasing dyspnoea at rest, not alleviated by drainage of pleural effusion

Russian Federation

Novartis Investigative Site

Recruiting

Moscow,115304,Russian Federation

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Recruiting

Irkutsk,664035,Russian Federation

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Recruiting

Ufa,450054,Russian Federation

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