A Prospective Observational Study to Describe Clinical Outcomes, Treatment Patterns, Patients Characteristics Among Patients With HR+/HER2- Advanced BC Initiating Treatment With Risarg®, Piqray®, Endocrine Therapy or Chemotherapy in Routine Clinica...

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A Prospective Observational Study to Describe Clinical Outcomes, Treatment Patterns, Patients Characteristics Among Patients With HR+/HER2- Advanced BC Initiating Treatment With Risarg® (Ribociclib), Piqray® (Alpelisib), Endocrine Therapy or Chemotherapy in Routine Clinical Practice in Russia

ClinicalTrials.gov Identifier:
NCT04943497

Novartis Reference Number:CLEE011ARU01

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 planned as a prospective multicenter NIS. This study is observational in nature and does not impose a therapy protocol, diagnostic/therapeutic interventions or a visit schedule. Patients with HR+/ HER2- advanced or metastatic BC that initiated treatment with ribociclib, alpelisib, mono endocrine therapy or chemotherapy will be included into the study across seven Russian districts. Patients will attend the sites in accordance with routine clinical practice. It is assumed that visits will be conducted every 3-4 months. Patients will undergo standard procedures and tests according to clinical guidelines and physician's judgement. 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. The recruitment period is planned for 24 months, observation period for maximum of 24 months, with total duration of study 4 years. Patients may discontinue from this NIS at any time.

Condition
Breast Cancer
Overall Status
Recruiting
Number of Participants
3290
Start Date
Jul 27, 2021
Completion Date
Jun 30, 2025

Gender
Female
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

aplelicib

There is no treatment allocation. Patients administered aplelicib by prescription that have started before inclusion of the patient into the study will be enrolled.
Other

chemotherapy

There is no treatment allocation. Patients administered chemotherapy by prescription that have started before inclusion of the patient into the study will be enrolled.
Other

mono endocrine therapy

There is no treatment allocation. Patients administered mono endocrine therapy by prescription that have started before inclusion of the patient into the study will be enrolled.
Other

ribociclib

There is no treatment allocation. Patients administered ribociclib by prescription that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Age ≥ 18 years at the moment of ribociclib, alpelisib, monoET or CT treatment initiation.
2. Female gender.
3. Confirmed diagnosis of locally advanced/metastatic not amenable to surgery HR+/HER2- BC (progressed following prior therapy or de novo) for whom the treating physicial took the decision to initiate treatment with ribociclib, alpelisib, monoET or CT before entering the study.
4. Patient who initiated treatment with ribociclib, alpelisib, monoET or CT no longer than 4 weeks (28 days) prior to written informed consent for this study.
5. Patients with ECOG performance status ≤ 2.
6. Provision of written informed consent.

Exclusion Criteria:

1. Patients with a life expectancy of less than 3 months at the time of aBC diagnosis 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 trial or NIS can be included as long as their standard of care is not altered by the study).
3. Patients receiving active treatment for malignancies other than BC at the time of enrollment.
4. Patients who are unable to understand the nature of the study.

Russian Federation

Novartis Investigative Site

Recruiting

Kaluga,248007,Russian Federation

Novartis Investigative Site

Recruiting

Pyatigorsk,357502,Russian Federation

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Recruiting

Cheboksary,428020,Russian Federation

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Recruiting

Vladivostok,690105,Russian Federation

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Recruiting

Moscow,143423,Russian Federation

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St Petersburg,197758,Russian Federation

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Recruiting

Syktyvkar,Komi Republic,167904,Russian Federation

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Recruiting

Khabarovsk,680042,Russian Federation

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Recruiting

Rostov-On-Don,344006,Russian Federation

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Recruiting

Voronezh,394036,Russian Federation

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Recruiting

Chelyabinsk,454087,Russian Federation

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Recruiting

Nalchik,360051,Russian Federation

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Recruiting

Tambov,392000,Russian Federation

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Surgut,Tymen Area,628402,Russian Federation

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Khanty-Mansiysk,628012,Russian Federation

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Saint Petersburg,191104,Russian Federation

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Ekaterinburg,620027,Russian Federation

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Nizhniy Novgorod,603081,Russian Federation

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Tula,300040,Russian Federation

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Recruiting

Arkhangelsk,163045,Russian Federation

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Kostroma,156005,Russian Federation

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Saransk,430032,Russian Federation

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Ekaterinburg,620036,Russian Federation

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Novosibirsk,630108,Russian Federation

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Tver,170008,Russian Federation

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Barnaul,656045,Russian Federation

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Krasnoyarsk,660022,Russian Federation

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Saratov,410053,Russian Federation

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Perm,614066,Russian Federation

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Simferopol,295023,Russian Federation

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