A Prospective Non-interventional Study to Evaluate Clinical Outcomes of Ribociclib Combined With Endocrine Therapy in Elderly Patients With HR+HER2 - Advanced Breast Cancer in Routine Clinical Practice in Russian Federation

Last Update: Jan 14, 2025

A Prospective Non-interventional Study to Evaluate Clinical Outcomes of Ribociclib Combined With Endocrine Therapy in Elderly Patients With HR+HER2 - Advanced Breast Cancer in Routine Clinical Practice in Russian Federation

ClinicalTrials.gov Identifier:

NCT06625333

Novartis Reference Number:CLEE011ARU06

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 study to evaluate the effectiveness, safety and quality of life in older patients (≥65 years) with HR+HER2- advanced breast cancer receiving ribociclib with ET in the first or second line in the real-life settings in Russia. In this study, an index event is a start of ribociclib+ET treatment. Post-index follow-up period is 24 months or until treatment discontinuation. The recruitment period is planned for 12 months. The interim analyses will be performed after enrollment is complete, and further one year later. Patients will visit 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.

Condition

HR+HER2- Advanced Breast Cancer

Overall Status

Recruiting

Number of Participants

328

Start Date

Oct 11, 2024

Completion Date

Oct 30, 2027

Gender

All

Age(s)

65 Years - 99 Years (Older Adult)

Eligibility Criteria

Inclusion Criteria:

1. Age ≥ 65 years at the moment of ribociclib+ET initiation
2. Female/Male gender
3. Confirmed diagnosis of locally advanced/metastatic not eligible for curative surgery HR+HER2- BC for whom the treating physician took the decision to initiate treatment with ribociclib+IA/FUL in the first or in the second line of the treatment
4. Patient who initiated treatment with ribociclib+IA/FUL no longer than 4 weeks (28 days) prior to written informed consent for this study
5. Provision of written informed consent.

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 within 3 years before BC diagnosis
4. Patients with active cardiac disease, or history of cardiac dysfunction, including prolonged QT interval corrected using Fridericia's formula (QTcF \> 450 msec).

Russian Federation

Novartis Investigative Site

Recruiting

Rostov On Don,344006,Russian Federation

Novartis Investigative Site

Recruiting

Kemerovo,650036,Russian Federation

Novartis Investigative Site

Recruiting

Arkhangelsk,163045,Russian Federation

Novartis Investigative Site

Recruiting

St Petersburg,194291,Russian Federation

Novartis Investigative Site

Recruiting

Khabarovsk,680042,Russian Federation

Novartis Investigative Site

Recruiting

Barnaul,656045,Russian Federation

Novartis Investigative Site

Recruiting

Tver,170008,Russian Federation

Novartis Investigative Site

Recruiting

Kirov,610021,Russian Federation

Novartis Investigative Site

Recruiting

Bryansk,241028,Russian Federation

Novartis Investigative Site

Recruiting

Ufa,450054,Russian Federation

Novartis Investigative Site

Recruiting

Krasnoyarsk,660022,Russian Federation

Novartis Investigative Site

Recruiting

Chelyabinsk,454080,Russian Federation

Novartis Investigative Site

Recruiting

Yaroslavl,150054,Russian Federation

Novartis Investigative Site

Recruiting

Obninsk,249036,Russian Federation

Novartis Investigative Site

Recruiting

Ekaterinburg,620036,Russian Federation

Novartis Investigative Site

Recruiting

Perm,614066,Russian Federation

Novartis Investigative Site

Recruiting

Irkutsk,664035,Russian Federation

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06625333*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06625333
2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com