Phase IIIb Study of Ribociclib + ET in Early Breast Cancer

Last Update: Jul 11, 2025
A Phase IIIb Study to Characterize the Efficacy and Safety of Adjuvant Ribociclib Plus Endocrine Therapy in a Close-to-clinical Practice Patient Population With HR+ HER2- Early Breast Cancer (Adjuvant WIDER)
ClinicalTrials.gov Identifier:
NCT05827081
Novartis Reference Number:CLEE011O12001
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

The purpose of this open-label, multicenter, phase IIIb, single-arm study is to characterize the efficacy and safety of the combination of ribociclib and standard adjuvant endocrine therapy (ET) on invasive breast cancer-free survival (iBCFS), in a close to clinical practice patient population with HR-positive (HR+), HER2-negative (HER2-), Anatomic Stage Group III, IIB, and a subset of Stage IIA Early Breast Cancer (EBC). The study consists of Screening, Treatment, and Follow-up periods.

* Treatment Period: all participants who complete screening will receive ribociclib 400 mg orally once daily on days 1 to 21 of a 28-day cycle, in combination with daily ET for 36 months (approximately 39 cycles) from the date of first dose. The Treatment Period starts when the patient receives their first dose of ribociclib and ends at the time of the 30-day Safety Follow-up. All treated participants should have a Safety Follow-up call conducted 30 days after the last dose of study treatment.
* Follow-up period: participants will be followed from 30 days after study treatment (i.e., ribociclib) completion/discontinuation (i.e. 30-day Safety Follow-up) until death, withdrawal of consent, lost to follow-up, or until 48 months after the last participant has received their first dose of study treatment (i.e. End of Study \[EOS\]), whichever occurs first.

Condition
Early Breast Cancer
Phase
Phase3
Overall Status
Recruiting
Number of Participants
1400
Start Date
Feb 28, 2024
Completion Date
Sep 20, 2030

Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Ansastrozole

Anastrozole 1 mg orally once daily continuously.
Drug

Exemestane

Exemestane 25 mg once daily continuously
Drug

Goserelin

Goserelin administered subcutaneously at 3.6 mg once every 4 weeks if the one-month depot formulation is used or at 10.8 mg once every 3 months if the three-month depot formulation is used
Drug

Letrozole

Letrozole 2.5 mg orally once daily continuously
Drug

Leuprolide

Leuprolide administered subcutaneously at 3.75 mg once every 4 weeks if the one-month depot formulation is used or at 11.25 mg once every 3 months if the three-month depot formulation is used
Drug

Ribociclib

Ribociclib 400 mg orally once daily on days 1-21 of a 28 day cycle followed by 7 days rest

Eligibility Criteria

Key Inclusion Criteria:

* Participant has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer (BC).
* Participant has HER2-negative breast cancer.
* Participants may have already received any standard neoadjuvant and/or adjuvant ET, including tamoxifen or toremifene at the time of informed consent signature, but enrollment should occur within 36 months of prior ET start date and participants should have at least 3 years remaining of endocrine adjuvant therapy.

* Participant has no contraindication to receive adjuvant ET in the study.
* Participant after surgical resection where tumor was removed completely, with the final surgical specimen microscopic margins free from tumor, and belongs to one of the following categories:

* Anatomic Stage Group III, or
* Anatomic Stage Group IIB, or
* A subset of Anatomic Stage Group IIA
* Participant has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1 or 2.
* Participant has adequate bone marrow and organ function.
* ECG values assessed by KardiaMobile-6L device, or standard 12-lead ECG per local investigator where KardiaMobile-6L cannot be used, as:

* QTcF interval at Screening \< 450 msec (QT interval using Fridericia's correction).
* Mean resting heart rate 50-99 beats per minute (determined from the ECG).

Key Exclusion Criteria:

* Participant with distant metastases of BC beyond regional lymph nodes (Stage IV according to AJCC 8th edition) and/or evidence of recurrence after curative surgery.
* Participant is concurrently using other antineoplastic therapy with the exception of adjuvant ET.
* Participant has any other concurrent severe and/or uncontrolled medical condition.
* Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality.
* Pregnant or breast-feeding (lactating) women or women who plan to become pregnant or breast-feed during the trial.

Other inclusion/exclusion criteria may apply

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