ForPatients
by Roche

Early Breast Cancer

A Study to Learn How Well Participants With a Specific Type of Early Breast Cancer (ER-Positive, HER2-Negative) Tolerate and Stay on Treatment With Giredestrant and How They Feel During Treatment

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07827573 2026-526742-27-00 BO46775

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IIIb, Single-arm, Open-Label, Multicenter Study Evaluating the Treatment Adherence, Tolerability, and Patient-Reported Outcomes of Giredestrant in Patients With Estrogen Receptor-Positive, HER2-Negative Early Breast Cancer

Trial Summary:

The purpose of this study is to evaluate treatment adherence, tolerability, and patient-reported outcomes of participants with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer (eBC) who are treated with giredestrant. The study will have two cohorts. Cohort A will comprise a broad upfront patient population with low-, medium-, or high-risk eBC. Cohort B will comprise patients with medium- or high-risk eBC who have completed adjuvant treatment with cyclin-dependent kinase 4 and 6 inhibitors (CDK4/6i) (abemaciclib or ribociclib) and endocrine therapy and who are now switching to giredestrant monotherapy.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically confirmed diagnosis of ER-positive, HER2-negative, Stage I-III, breast cancer
- Definitive surgery of primary breast tumor(s) and axillary lymph nodes (axillary lymph node dissection and/or sentinel lymph node biopsy)
- Participants must have completed any prior adjuvant chemotherapy before enrollment, if given
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0, 1, or 2
- Adequate organ function
- Men and pre- or perimenopausal women must receive a concurrent approved luteinizing hormone-releasing hormone agonist

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within the timeframe in which contraception is required
- Diagnosis of inoperable locally advanced or Stage IV breast cancer
- History of any prior (ipsilateral and/or contralateral) invasive breast cancer or ductal carcinoma in situ (DCIS)
- Planned surgery during the study
- Prior treatment with giredestrant, selective estrogen receptor degraders (SERDs), or investigational endocrine agents
- Active cardiac disease or history of cardiac dysfunction