ForPatients
by Roche

Early Breast Cancer

A Study Evaluating Adherence, Tolerability, and Patient Reported Outcomes of Giredestrant in Participants With ER+/HER2- Early Breast Cancer Who Are Intolerant to Adjuvant Aromatase Inhibitor Therapy (novERA Breast Cancer)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07541079 GO46747

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 Study Evaluating Adherence, Tolerability, and Patient Reported Outcomes (PRO) of Giredestrant in Patients With ER+/HER2- Early Breast Cancer Who Are Intolerant to Adjuvant Aromatase Inhibitor Therapy

Trial Summary:

The purpose of this study is to understand treatment adherence and patient-reported outcomes of switching to giredestrant due to prior aromatase inhibitor (AI) intolerance. Giredestrant will be administered as adjuvant endocrine therapy for participants with low-, medium-, and high-risk, Stage I-III, histologically confirmed, estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-), early breast cancer (eBC), as defined by the investigator. Participants will enroll if considered to be intolerant to a prior adjuvant AI therapy.

Genentech, Inc.
Sponsor

Phase 3
Phase

NCT07541079 GO46747
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years	No

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Inclusion Criteria:

- Considered appropriate for treatment with endocrine therapy (ET)
- Histologically confirmed diagnosis of ER+/HER2-, Stage I-III (low-/medium-/high-risk) early breast cancer (eBC)
- Documented ER+ tumor according to American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP), defined as #1% of tumor cells stained positive
- Documented HER2- tumor according to ASCO/CAP
- Postmenopausal females at the time of signing the Informed Consent Form
- Documented use of a prior adjuvant aromatase inhibitor (AI) (i.e., anastrozole, exemestane, or letrozole) for a total of #6 months
- Documented use of an adjuvant AI (i.e., anastrozole, exemestane, or letrozole) for the consecutive #3 months immediately prior to consent
- Participant and investigator agree that current symptoms on AI are intolerable and warrant a switch in therapy to attempt sustained treatment
- Documented Grade 2 or 3 adverse events, per NCI CTCAE v6.0, determined by the investigator to be associated with AI therapy's intolerance
- Participant and investigator planning the first switch from an AI
- Has completed the following: (neo)adjuvant chemotherapy (if administered), definitive surgery of primary breast tumor(s) and/or axillary lymph nodes dissection (ALND) and/or sentinel lymph node biopsy (SLNB) and/or radiotherapy
- Eastern Cooperative Oncology Group Performance (ECOG) Performance Status 0 or 1

Exclusion Criteria:

- Participation within 6 months before enrollment in any other clinical study involving an investigational adjuvant treatment including anti-cancer agents
- Diagnosis of rheumatoid arthritis, psoriatic arthritis, or other inflammatory connective tissue disease
- Any prior fulvestrant or any oral selective estrogen receptor degraders (SERDs)
- Have active cardiac disease or history of cardiac dysfunction
- Have clinically significant liver disease consistent with Child-Pugh Class B or C, including active hepatitis (e.g., hepatitis B virus [HBV] or hepatitis C virus [HCV]), current alcohol abuse, cirrhosis, or positive test for viral hepatitis
- Treatment with strong CYP3A inhibitors or inducers within 14 days or 5 drug elimination half-lives (whichever is longer) prior to initiation of study treatment
- Have had any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes an individual's safe participation in and completion of the study