ForPatients
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Breast Cancer Er-PositiveBreast Cancer HER-2 NegativeLocally Advanced or Metastatic Breast CancerBreast CancerEstrogen Receptor (ER)-Positive

A Study Evaluating the Efficacy and Safety of Giredestrant Plus Everolimus Compared With the Physician's Choice of Endocrine Therapy Plus Everolimus in Participants With Estrogen Receptor-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer (evERA Breast Cancer)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	13 Countries	NCT05306340 2022-000199-20 2023-506821-12-00 ML43171

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 III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Giredestrant Plus Everolimus Compared With the Physician's Choice of Endocrine Therapy Plus Everolimus in Patients With Estrogen Receptor-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer

Trial Summary:

This Phase III, randomized, open-label, multicenter study will evaluate the efficacy and safety of giredestrant plus everolimus compared with the physician's choice of endocrine therapy plus everolimus in participants with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer who have had previous treatment with cyclin-dependent kinase 4/6 inhibitors (CDK4/6is) and endocrine therapy, either in the locally advanced/metastatic or the adjuvant setting.

Genentech, Inc.
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

Inclusion Criteria:

- Locally advanced unresectable or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent
- Documented estrogen receptor-positive (ER+) tumor and HER2-negative tumor, assessed locally
- Ability to provide a blood sample for circulating-tumor deoxyribonucleic acid (ctDNA) Estrogen Receptor 1 (ESR1) mutation status determination by central testing
- Prior endocrine therapy (ET) in combination with cyclin-dependent kinase 4/6 inhibitors in either setting as follows:
- Metastatic setting: Disease progression after #6 months on ET plus CDK4/6 inhibitor in the locally advanced or metastatic setting. If ET plus CDK4/6 inhibitor is not the most recent therapy, then patient must also have had disease progression after #4 months on most recent ET
- Adjuvant Setting: Relapse either while taking or within 12 months of exposure to combination adjuvant ET and CDK4/6 inhibitor. Patients must have taken at least 12 months of adjuvant ET, 6 months of which was in combination with a CDK4/6 inhibitor.
- Measurable disease as defined per RECIST v.1.1 or evaluable bone metastases. Patients with evaluable bone disease in the absence of measurable disease outside of the bone must have at least one predominantly lytic bone lesion confirmed by computed tomography (CT) or magnetic resonance imaging (MRI) which can be followed
- Eastern Cooperative Oncology Group Performance Status 0-1
- For women who are premenopausal or perimenopausal and for men: treatment with approved luteinizing hormone-releasing hormone (LHRH) agonist therapy for the duration of study treatment

Exclusion Criteria:

- Prior treatment with another oral selective estrogen receptor degrader (SERD), proteolysis targeting chimera (PROTAC), complete estrogen receptor antagonist (CERAN), novel oral selective estrogen receptor modulator (SERM), or everolimus in any setting. Prior fulvestrant is allowed if treatment was terminated at least 28 days prior to randomization. Prior treatment with tamoxifen is allowed.
- Progression on more than 2 prior lines of systemic endocrine therapy in the locally advanced unresectable or metastatic breast cancer setting
- Prior chemotherapy for locally advanced unresectable or metastatic disease
- Treatment with strong Cytochrome P450 3A4 (CYP3A4) inhibitors or inducers within 14 days or 5 drug elimination half-lives (whichever is longer) prior to randomization
- Treatment with any investigational therapy within 28 days prior to initiation of study treatment
- Major surgery, chemotherapy, radiotherapy, or other anti-cancer therapy within 14 days prior to randomization
- History of any other malignancy other than breast cancer within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, nonmelanoma skin carcinoma, papillary thyroid cancer treated with surgery, Stage I endometrial cancer, or other non-breast cancers at very low risk of recurrence
- Advanced, symptomatic, visceral spread that is at risk of life-threatening complications in the short term
- Known active uncontrolled or symptomatic central nervous system (CNS) metastases, carcinomatous meningitis, or leptomeningeal disease
- Active cardiac disease or history of cardiac dysfunction
- Known clinically significant history of liver disease consistent with Child-Pugh Class B or C including active viral or other hepatitis virus, current alcohol abuse, or cirrhosis
- Active inflammatory bowel disease, chronic diarrhea, short bowel syndrome, or major upper gastrointestinal (GI) surgery including gastric resection

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- Interstitial lung disease or severe dyspnea at rest or requiring oxygen therapy
- Serious infection requiring oral or intravenous (IV) antibiotics, or other clinically significant infection, within 14 days prior to randomization
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- Known allergy or hypersensitivity to any of the study drugs or any of their excipients
- For premenopausal or perimenopausal women and for men: known hypersensitivity to LHRH agonists
- Pregnant or breastfeeding

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