ForPatients
by Roche

Early Breast CancerBreast Cancer Er-PositiveBreast Cancer HER-2 NegativeBreast Cancer

A Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared With Physician's Choice of Adjuvant Endocrine Monotherapy in Participants With Estrogen Receptor-Positive, HER2-Negative Early Breast Cancer (lidERA Breast Cancer)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	54 Countries	NCT04961996 2021-000129-28 2023-507172-44-00 GO42784

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 Adjuvant Giredestrant Compared With Physician's Choice of Adjuvant Endocrine Monotherapy in Patients With Estrogen Receptor-Positive, HER2-Negative Early Breast Cancer

Trial Summary:

This is a Phase III, global, randomized, open-label, multicenter, study evaluating the efficacy and safety of adjuvant giredestrant compared with endocrine therapy of physician's choice in participants with medium- and high-risk Stage I-III histologically confirmed estrogen receptor (ER)-positive and human epidermal growth factor receptor 2 (HER2)-negative early breast cancer. In addition, an open-label exploratory substudy will explore the safety and efficacy of giredestrant in combination with abemaciclib in a subset of the primary study population.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04961996 2021-000129-28 2023-507172-44-00 GO42784
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

Primary Study Inclusion Criteria:

- Documented estrogen receptor (ER)-positive and HER2-negative breast tumor, as assessed locally on a primary disease specimen
- Participants who have multicentric (the presence of two of more tumor foci within different quadrants of the same breast) and/or multifocal (the presence of two or more tumor foci within a single quadrant of the breast) breast cancer are also eligible if all examined tumors meet pathologic criteria for ER positivity and HER2 negativity
- Participants must have undergone definitive surgery of their primary breast tumor(s) and axillary lymph nodes (axillary lymph node dissection [ALND] and/or sentinel lymph node biopsy [SLNB])
- Participants who received or will be receiving adjuvant chemotherapy must have completed adjuvant chemotherapy prior to randomization. Participants may also have received neoadjuvant chemotherapy. A washout period of at least 21 days is required between last adjuvant chemotherapy dose and randomization.
- Resolution of all acute toxic effects of prior anti-cancer therapy or surgical procedures to NCI CTCAE v5.0 Grade 1 or better (except alopecia, Grade #2 peripheral neuropathy, arthralgia or other toxicities not considered a safety risk for the participant per the investigator's judgment)
- Participants have received (neo)adjuvant chemotherapy and/or had surgery and had no prior endocrine therapy are eligible, provided that they are enrolled within 12 months following definitive breast cancer surgery
- Participants who have confirmed availability of an untreated primary breast tumor tissue specimen suitable for biomarker testing (i.e., representative archived formalin-fixed, paraffin-embedded [FFPE] tissue block [preferred] or 15-20 slides containing unstained, freshly cut, serial sections), with associated de-identified pathology report is required. Although 15-20 slides are preferred, if only 10-14 slides are available, the individual may still be eligible for the study.
- Participants with node-positive and node-negative disease are eligible provided they meet additional risk criteria as defined in the protocol
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0, 1, or 2
- Able and willing to swallow, retain, and absorb oral medication
- Adequate organ function

Substudy Inclusion Criteria:

To be eligible for substudy participation, in addition to meeting the inclusion criteria in the primary protocol, participants must also meet the following modified criteria:

- Patients who received adjuvant radiotherapy must have completed radiotherapy prior to enrollment, and patients must have recovered (to Grade #1) from the acute effects of radiotherapy. A washout period of at least 14 days is required between end of radiotherapy and enrollment.

Exclusion Criteria:

Primary Study Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 10 days after the final dose of giredestrant, or within the time period specified per local prescribing guidelines after the final dose of the endocrine therapy of physician's choice

- Received treatment with investigational therapy within 28 days prior to initiation of study treatment or is currently enrolled in any other type of medical research judged by the sponsor not to be scientifically or medically compatible with this study
- Receiving or planning to receive a CDK4/6 inhibitor as (neo)adjuvant therapy. A short course of up to 12 weeks of neoadjuvant or adjuvant treatment with CDK4/6 inhibitor therapy prior to randomization is allowed.
- Active cardiac disease or history of cardiac dysfunction
- Diagnosed with Stage IV breast cancer
- A history of any prior (ipsilateral and/or contralateral) invasive breast cancer or ductal carcinoma in situ (DCIS). Participants with a history of contralateral DCIS treated by only local regional therapy at any time may be eligible.
- A history of any other malignancy within 3 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, nonmelanoma skin carcinoma, or Stage I uterine cancer
- Any prior endocrine treatment with selective ER modulators (e.g., tamoxifen), degraders, or aromatase inhibitors. A short course of neoadjuvant or adjuvant endocrine therapy (up to 12 weeks) is allowed.
- 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 CYP3A4 inhibitors or inducers within 14 days or 5 drug elimination half-lives (whichever is longer) prior to initiation of study treatment
- Known allergy or hypersensitivity to any of the study drugs or any of their excipients
- Pre- and perimenopausal participants or male participants who have a known hypersensitivity to LHRH agonists
- A documented history of hemorrhagic diathesis, coagulopathy, or thromboembolism
- Renal dysfunction that requires dialysis
- A major surgical procedure unrelated to breast cancer within 28 days prior to randomization
- A serious infection requiring oral or IV antibiotics within 14 days prior to screening or other clinically significant infection (e.g., COVID-19) within 14 days prior to screening
- 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
- Unable or unwilling to comply with the requirements of the protocol in the opinion of the investigator

Substudy Exclusion Criteria:

Potential participants are excluded from the substudy if any criteria from t\he primary study or the following criteria apply:

- Prior participation in the GO42784 primary study
- Received a CDK4/6i as (neo)adjuvant therapy prior to enrollment
- Treatment with moderate CYP3A inducers, strong CYP3A inducers or strong CYP3A inhibitors within 14 days or 5 drug elimination half-lives (whichever is longer) prior to initiation of study treatment