lidERA Breast Cancer: A study of giredestrant as single-agent adjuvant therapy in patients with ER-positive, HER2-negative early breast cancer

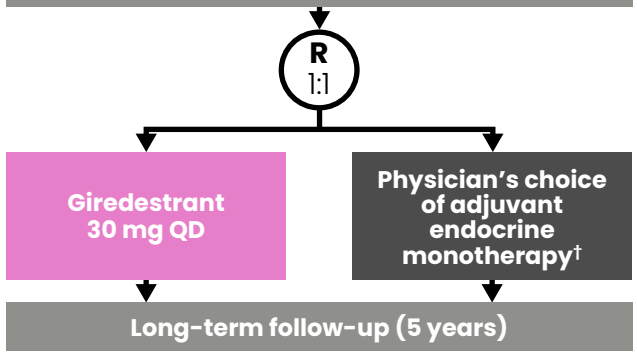
Roche

Enrolling now

lidERA Breast Cancer/GO42784: A Phase III, randomised, open-label, multicentre study evaluating the efficacy and safety of adjuvant giredestrant compared with physician's choice of adjuvant endocrine monotherapy in patients with ER-positive, HER2-negative early breast cancer (eBC)

Patients with ER-positive, HER2-negative eBC
- Medium- or high-risk disease
- Postmenopausal or pre-/peri-menopausal women, and men*
- Prior surgery with curative intent
- Completed (neo)adjuvant chemotherapy (if administered) and/or surgery <12 months prior to enrolment; ≤4 weeks of prior endocrine therapy

N = 4100



Patients are categorised as medium- or high-risk based on anatomical (tumour size, nodal status) and biological features (grade, Ki67, gene signatures [OncotypeDx or MammaPrint] if available)

* For men and pre-/peri-menopausal women, LHRH agonist will be administered according to local prescribing information.

† Physician's choice of adjuvant endocrine monotherapy refers to either tamoxifen, anastrozole, letrozole or exemestane to be dosed according to prescribing information.

Primary endpoint

- Invasive disease-free survival (IDFS), excluding second primary non-breast cancers; time from randomisation to the occurrence of IDFS events.

Secondary endpoints

- Overall survival
- IDFS (per STEEP‡) including second primary non-breast cancer
- Disease-free survival
- Distant recurrence-free interval
- Locoregional recurrence-free interval
- Safety
- Pharmacokinetics
- Patient-reported outcomes

‡ STEEP System as defined by Hudis CA, *et al. J Clin Oncol* 2007; **25:**2127–2132.

Key inclusion criteria

- Women and men ≥18 years
- Locally confirmed ER+, HER2− tumours (ASCO/CAP)
- Participants with multicentric and/or multifocal breast cancer are eligible if all examined tumours meet pathological criteria for ER-positive, HER2-negative
- Participants who received adjuvant chemotherapy must have completed a ≥21 day washout prior to randomisation
  - Participants who are not candidates for adjuvant chemotherapy or decline chemotherapy are permitted
- Must have undergone definitive surgery of primary breast tumour(s) with tumour-free margins
- Resolution of all acute toxic effects of prior anti-cancer therapy or surgical procedures
- Participants who have had (neo)adjuvant chemotherapy and/or surgery and no prior endocrine therapy are eligible, provided that they are enroled within 12 months following definitive breast cancer surgery
- Tumour tissue specimen suitable for biomarker testing
- Participants with node-positive and node-negative disease are eligible provided they meet additional risk criteria as defined in the protocol
- ECOG PS 0–2
- Adequate organ function

Key exclusion criteria

- Prior treatment with investigational therapy within 28 days prior to initiation of study treatment
- Prior endocrine treatment with selective ER modulators, degraders, or aromatase inhibitors, except that up to 12 weeks neoadjuvant or adjuvant endocrine therapy is allowed
- Receiving or planning to receive a CDK4/6i as adjuvant therapy
  - Short course of ≤12 weeks of (neo)adjuvant treatment with CDK4/6i therapy prior to randomisation is allowed
- Active cardiac disease or history of cardiac dysfunction
- Stage IV (metastatic) BC
- Prior history of invasive BC or DCIS
- Other malignancy within 3 years prior to screening
- A known clinically significant history of liver disease
- For women of premenopausal or perimenopausal status or men: known hypersensitivity to LHRH agonists
- History of haemorrhagic diathesis, coagulopathy or thromboembolism
- Uncontrolled inflammatory bowel disease or chronic diarrhoea, short bowel syndrome or major upper gastrointestinal surgery
- Serious infection requiring oral or IV antibiotics or other clinically significant infection within 14 days prior to screening

lidERA Breast Cancer is enrolling in: Argentina, Australia, Austria, Belgium, Bosnia and Herzegovina, Brazil, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czechia, Finland, France, Georgia, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Kenya, Republic of Korea, Latvia, Malaysia, Mexico, Netherlands, North Macedonia, Philippines, Poland, Portugal, Romania, Russian Federation, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Kingdom, United States

For more information about enrolment to this trial, and which sites are participating, please contact global-roche-genentech-trials@gene.com

Link for more information

https://clinicaltrials.gov/ct2/show/NCT04961996

Please reach out to your local Roche/Genentech contact for more information

Date of Preparation: September 2022
M-XX-00010665