IdEra Breast Cancer: A phase III adjuvant study of giredestrant (GDC-9545) vs physician’s choice of endocrine therapy in patients with estrogen receptor+, HER2− early breast cancer

**BACKGROUND**

- Endocrine therapies (ETs) that target estrogen receptor (ER) activity and/or estrogen synthesis are the mainstay of ER+ breast cancer (BC) treatment.
- Despite best management, many patients (pts) with ER+ HER2− early BC (eBC) develop resistance in some cases due to the acquisition of tumor mutations in ERα (that can drive estrogen-independent transcription and proliferation) and/or in estrogen receptor (ER) coactivators.
- New treatment alternatives for ER+ HER2− eBC are needed to reduce risk of recurrence and improve survival, tolerability, quality of life, and adherence.

**Giredestrant** is a novel, potent, nonselective oral selective ER antagonist and degrader (SERD) that achieves high ER occupancy and is active against tumors that retain ER-sensitivity, including ER+ tumors (with or without coactivators).

**This study** is currently open for enrollment.

- 210/400 pts have been enrolled globally (Figure 2).
- This study is conducted in partnership with TRIO Oncology and NSABP.
- Consistent efforts are being made to enroll a diverse and inclusive population.

**STUDY ENDPOINTS**

- Primary endpoint: Invasive disease-free survival (DFS), excluding second primary non-BC, the time from randomization to the occurrence of DFS events.
- Secondary endpoints:
  - Distant recurrence-free interval.
  - Locoregional recurrence-free interval.
  - Safety. Patient-reported outcomes.

**STUDY THERAPY**

- Giredestrant will be given orally at 30 mg daily, standard ET, according to prescribing information. For men and pre/perimenopausal women, luteinizing hormone-releasing hormone will be administered according to local prescribing information.
- Study therapy will be given for 5 years.
- 30 mg giredestrant was selected for phase II assessment, as it is well tolerated with promising antitumor activity, and has similar activity to dose >30 mg.

**PATIENT SUPPORT & INCLUSIVE RESEARCH**

- IdEra BC aims to ensure racial and ethnic diversity and expand clinical trial access (Supplemental Figure 1).
- Various programs and activities, including digital healthcare solutions, aim to support patients on their journey (Supplemental Figure 1).

**STATISTICAL ANALYSIS**

- The primary endpoint analysis will use a stratified log-rank test at an overall 0.05 significance level (two-sided).
- An interim analysis and a full statistical plan are available, and an independent data monitoring committee will be in place.

**CONFLICTS OF INTEREST**

- PS reports consulting fees (e.g., advisory boards) from AstaZeneca, Boyer, Boehringer Ingelheim, Merck, Novartis, Pfizer, and F. Hoffmann-La Roche Ltd.
- PS and employment (spouse) by F. Hoffmann-La Roche Ltd. Please refer to the abstract for all author conflicts.

**ACKNOWLEDGMENTS**

We thank the pts who are participating in this study, and their families, as well as the staff research coordinators, and investigators at every participating institution. Support for third-party writing assistance for this paper is provided by Daniel Doyle, PhD, of Health Interactions, was provided by F. Hoffmann-La Roche Ltd.

**REFERENCES**


**CONTACT INFORMATION**

- Email: global.roche@genentech.com
- Phone: 1-888-664-4278 (USA only).
- https://bit.ly/3T0BbDl