IdiERA Breast Cancer: A Phase IIIAdjuvant study of giredestrant (GDC-9545) vs physician’s choice of endocrine therapy (ET) in patients (pts) with estrogen receptor-positive, HER2-negative early breast cancer (ER+/HER2– eBC)

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BACKGROUND

• Intrinsic ER+ breast cancer (BC) (estrogen receptor-positive, HER2-negative) has a diverse and inclusive population.
• Target enrollment is 4100 pts globally on all arms.
• The primary endpoint is invasive disease-free survival (IDFS), the time from randomization to the occurrence of IDFS events.

STUDY OVERVIEW

• This is a phase III, global, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredestrant vs physician’s choice of adjuvant ET in pts with median- and high-risk stage I-II histologically confirmed ER+/HER2– eBC (NCT04464744; Figure 1).

STUDY DESIGN

• Eligible pts (Table 1) are randomized 1:1 to giredestrant or physician’s choice of endocrine therapy (ET), tamoxifen, anastrozole, letrozole, or exemestane (see Table 1).
• Target enrollment is 4100 pts globally on all arms.
• The primary endpoint is invasive disease-free survival (IDFS), the time from randomization to the occurrence of IDFS events.

Primary endpoint

• Invasive disease-free survival (IDFS), the time from randomization to the occurrence of IDFS events.

Secondary endpoints

• Locoregional recurrence-free interval.
• Distant recurrence-free interval.
• Disease-free survival.

Table 1: Key eligibility criteria

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<th>Key eligibility criterion</th>
<th>Key exclusion criteria</th>
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<td>Locally confirmed ER+/HER2– tumors (ASC/CC/MP)</td>
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Figure 1: Study design

• This study is currently open for enrollment.

Figure 2: Participating countries

• Target enrollment is 4100 pts globally on all continents (Figure 2).

Figure 3: Pharmacokinetics

• This study is conducted in partnership with TRC Oncology and NIDAAP.

• Concerted efforts are made to enroll a diverse and inclusive population.

STUDY ENDPOINTS

• Giredestrant will be given orally at 30 mg every day; standard ET, agent or in combination with palbociclib.

• Giredestrant has been demonstrated to be more potent and degrader (SERD); it achieves robust ER occupancy and is active in vivo.

• 30 mg giredestrant was selected for phase III assessment, as it is well tolerated with promising antitumor activity, tolerability, quality of life, and safety.

• Pharmacokinetics

• Patient-reported outcomes.

PREFERENCES


• See poster PD13-06 for a cardiac analysis of the same study; and spotlight poster OT2-11-09 and has similar activity to

• Target enrollment is 4100 pts globally on all

• The interim results of the first phase II, randomized clinical trial of giredestrant in the eBC setting, the coopERA Breast Cancer (NCT04464744) study, showed that the relative reduction of Ki67 after giredestrant in the eBC setting, the coopERA Breast Cancer (NCT04464744) study, showed that the relative reduction of Ki67 on adjuvant giredestrant vs physician’s choice of endocrine therapy (ET) in patients (pts) with estrogen receptor-positive, HER2-negative early breast cancer (ER+/HER2– eBC) is 1.4 (95% CI 1.1-1.7).

• PD13-06 for the primary analysis (following an encouraging interim analysis) of the first randomized phase II study that targets the same activity (giredestrant in the setting of a single agent or in combination with palbociclib) of
cancEra Breast Cancer: A phase III adjuvant study of giredestrant (GDC-9545) vs physician’s choice of endocrine therapy (ET) in patients (pts) with estrogen receptor-positive, HER2-negative early breast cancer (ER+/HER2– eBC)

• This study is sponsored by F. Hoffmann-La Roche Ltd.

• All authors have received research support in the form of

• The primary endpoint analysis will use a stratified log-rank test at an overall significance level of 0.05.

• An interim analysis and a full analysis plan are planned, and an independent data monitoring committee will be in place.

• We thank the patients and their families who are participating in this study, as well as the staff, research coordinators, and investigators at each participating institution. Support for third-party writing assistance for this poster, furnished by Daniel Clyde, PhD, of Health Interactions, was provided by F. Hoffmann-La Roche Ltd.

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