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Patient (pt)-reported outcomes (PROs) from the Phase III lidERA Breast Cancer (BC) trial of giredestrant (GIRE) in pts with oestrogen receptor-positive, HER2-negative early BC (ER+, HER2- eBC)

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Background

In the adjuvant treatment (tx) of eBC, understanding the pt experience is critical, as long-term tolerability and health-related quality of life (HRQoL) directly impact adherence and outcomes. The Phase III lidERA BC trial (NCT04961996; Bardia SABCS 2025) demonstrated a significant efficacy benefit of GIRE—an oral selective ER degrader and full ER antagonist—over standard-of-care endocrine therapy (SOC ET). To complement the study's clinical efficacy, this PRO analysis evaluated function, HRQoL, toxicity and tx burden from the pt perspective.

Methods

Pts with ER+, HER2- eBC who had surgery and (neo)adjuvant chemotherapy (if indicated) were randomised 1:1 to once-daily 30 mg GIRE or SOC ET (tamoxifen/aromatase inhibitor). Predefined secondary and exploratory PRO endpoints were assessed via EORTC QLQ-C30, PRO-CTCAE and FACT-G item GP5 at scheduled timepoints. Descriptive analyses over time were conducted.

Results

At data cutoff (median follow-up 32.3 months), questionnaire completion rates were > 75% across 4170 pts at baseline and remained > 75% through most cycles. Pts in both arms maintained their baseline physical/role function and HRQoL while on tx, with no clinically meaningful deterioration observed (change of ≥ 10 points). Tolerability profiles were similar in both arms, with most pts reporting key symptoms (eg joint pain, hot flashes, fatigue) at levels 'occasionally'/'mild'/'a little bit' or less. The proportions of pts experiencing worsening of key symptoms to high severity levels (score 3 or 4) were comparable between arms, including joint pain (43% GIRE vs 43% SOC ET), hot flashes (32% vs 31%) and fatigue (19% vs 20%). Through 42 cycles, 2–8% more GIRE- vs SOC ET-treated pts reported being 'not at all' bothered by side effects at each visit.

Conclusions

PRO data from lidERA BC demonstrated that tx with GIRE in pts with eBC preserved pt's day-to-day function and HRQoL. While frequency and severity of key symptoms were comparable between arms, pts on GIRE consistently reported less bother from side effects. In summary, PRO data suggest that the improved efficacy of GIRE over SOC ET is achieved without compromising tolerability or HRQoL.

Clinical trial identification

NCT04961996.

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