A Phase 3 randomised open-label study of extended adjuvant therapy with camizestrant vs standard endocrine therapy in patients with ER+/HER2– early breast cancer and an intermediate or high risk of recurrence (CAMBRIA-1)

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Plan language summary

Why are we performing this research?

- To demonstrate the efficacy and safety of extending adjuvant therapy with camizestrant versus standard endocrine therapy in patients with ER+/HER2– early breast cancer and an intermediate or high risk of recurrence.

How are we performing this research?

- Patients will be randomised to receive either camizestrant (150 mg or 200 mg) or standard endocrine therapy (aromatase inhibitor or tamoxifen).

Who will participate in this study?

- Women who have completed definitive locoregional therapy and are receiving adjuvant endocrine therapy.

Where can I access more information?

- Visit the study website for more information: [Study Website].

Key inclusion criteria

- Pre-menopausal or post-menopausal women or men, ≥18 years old
- Histologically confirmed invasive breast cancer or carcinoma in situ of the cervix
- Hormone receptor-positive
- HER2-negative
- Nodes: 0

Key exclusion criteria

- Known metastatic disease
- Prior HER2-directed therapy
- Prior neoadjuvant therapy for primary breast cancer
- Incomplete response to neoadjuvant therapy
- Incomplete locoregional therapy
- Significant comorbidities

Camizestrant in ER+/HER2– BC

- A Phase 3 randomised, open-label trial to compare the efficacy and safety of extending adjuvant therapy with camizestrant versus standard endocrine therapy in patients with ER+/HER2– early BC who have completed definitive locoregional therapy and are receiving adjuvant endocrine therapy.

Current treatment of ER+/HER2– early BC

- The recommended duration of adjuvant ET is dependent on risk.
- A meta-analysis of clinical trials of post-menopausal women with ER+ early BC showed that a switch to AI after 2 years of tamoxifen significantly reduced the risk of recurrence.

Reducing the risk of recurrence in ER+/HER2– early BC

- There is evidence that incorporating a more effective ET after 2 years of standard adjuvant ET can result in clinical benefit.

Rationale for extended adjuvant therapy with camizestrant in patients with ER+/HER2– early BC and an intermediate or high risk of recurrence

- Camizestrant is a drug that blocks and degrades estrogen receptors on cancer cells, which can help reduce the risk of recurrence.

Plan study endpoints

- Primary: IDFS
- Secondary: OS, PFS, IDFS, HR, LHRH, LRRH, LBCF, LRRH, LBCF

Invasive disease-free survival (IDFS): defined as the time from randomisation to the date of first distant recurrence or death due to any cause.

Study locations:

- Enrollment is ongoing; 682 patients from 73 countries have been enrolled.

References