EMERALD

TRIAL TITLE

Phase 3 Trial of Elacestrant vs. Standard of Care for the Treatment of Patients with ER+/ HER2- Advanced Breast Cancer

TRIAL STATUS

Not Recruiting

TRIAL NUMBER

NCT03778931

TRIAL PHASE

Phase 3

PARTICIPANTS IN THE STUDY

- 18 years of age or older
- Diagnosed with ER-positive/ HER2-negative breast cancer that is advanced or metastatic.
- Each participant's cancer must have progressed after treatment with a CDK4/6 inhibitor in combination with fulvestrant or an aromatase inhibitor.
- Participants may have received chemotherapy.

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BREAST CANCER breakthroughs

Breast Cancer Breakthroughs

FACT SHEET

TRIAL DETAILS:

- 477 participants were randomized to receive a new hormone therapy called elacestrant or the standard of care hormone therapy (fulvestrant or aromatase inhibitor).
- The elacestrant pill was given daily until cancer progressed.
- Each participant's tumor was tested for ESR1 mutations using a liquid biopsy (blood sample) with the Guardant360 CDx test.

ER-POSITIVE/HER2-NEGATIVE BREAST CANCER AND EMERALD TRIAL RESULTS:

- The second-line standard of care for patients with metastatic ER-positive/HER2- breast cancer is hormone therapy consisting of fulvestrant or an aromatase inhibitor.[1]
- Progression on first-line standard of care consisting of a CDK4/6 inhibitor in combination with hormone therapy is associated with developing ESR1 gene mutations in the tumor.[1]
- The EMERALD trial found that in patients with ESR1 mutations, cancer remained stable after 12 months in 26.8% of patients taking elacestrant compared to 8.2% of patients receiving the standard of care.[1]
- Updated results from the EMERALD trial also showed that those taking CDK4/6 inhibitors for a year or more during first-line treatment had cancer that remained stable for a median of 8.6 months compared to 1.9 months for those receiving standard of care.[2]
- Elacestrant was FDA-approved to treat advanced or metastatic ER-positive breast cancers in postmenopausal women with mutations in the ESR1 gene on January 27, 2023.[3]
- The most common side effects of elacestrant are nausea, fatigue, vomiting, decreased appetite, joint pain and diarrhea.[1]

REFERENCES:

1. Bidard F. et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: Results from the randomized phase III EMERALD Trial. Journal of Clinical Oncology. 2023. DOI: https://doi.org/10.1200/JCO.22.00338
2. Bardia et al. EMERALD phase 3 trial of elacestrant versus standard of care endocrine therapy in patients with ER+/HER2- metastatic breast cancer: Updated results by duration of prior CDK4/6i in metastatic setting. 2022 San Antonio Breast Cancer Symposium. Abstract GS3-01, December 8, 2022.
3. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-elacestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast-cancer