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.

For more information, go to komen.org/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.
• 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.
• 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.
• 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.
• 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.
• The most common side effects of elacestrant are nausea, fatigue, vomiting, decreased appetite, joint pain and diarrhea.

REFERENCES:
3. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-elacestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast-cancer