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

OVERVIEW

Study type: Interventional
Study phase: III
Condition: Breast cancer
Intervention:
  • Elacestrant
  • Standard of care:
    o Fulvestrant
    o Anastrozole
    o Letrozole
    o Exemestane

Study IDs:
  • Clinicaltrials.gov identifier: NCT03778931
  • Sponsor protocol number: 1901-308

Clinicaltrials.gov link: https://clinicaltrials.gov/ct2/show/study/NCT03778931?term=elacestrant&rank=1
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Study PI: Christopher Croot, MD
Status: Open to accrual

ABOUT THIS STUDY

This Phase 3 clinical study compares the efficacy and safety of elacestrant to the standard of care (SOC) options of fulvestrant or an aromatase inhibitor (AI) in women and men with breast cancer whose disease has advanced on at least one endocrine therapy including a CDK4/6 inhibitor in combination with fulvestrant or an aromatase inhibitor (AI).

PARTICIPATION ELIGIBILITY

Participant eligibility includes age, gender, type and stage of disease, and previous treatments or health concerns. Eligibility requirements differ from study to study, and identify who can or cannot participate. If you need assistance understanding the eligibility criteria, please contact the study team.
PRE-REGISTRATION ELIGIBILITY CRITERIA:

1. Must have a histologically-or cytologically-proven diagnosis of adenocarcinoma of the breast with evidence of either locally advanced disease not amendable to resection or radiation therapy with curative intent or metastatic disease not amendable to curative therapy.
2. Must be appropriate candidates for endocrine monotherapy.
3. Must have measurable disease or, nonmeasurable (evaluable) bone-only disease.
4. Female or male ≥ 18 years of age.
5. Female subjects must be post-menopausal women, defined by one of the following criteria:
   a. Documented bilateral surgical oophorectomy
   b. Age ≥ 60 years with amenorrhea ≥1 year since last menses
   c. Age <60 years with amenorrhea ≥1 year since last menses with no alternative pathological or physiological cause
6. Male subjects must not allow pregnancy with their sperm (abstain, do not donate sperm, etc)
7. Must have ER+, HER2- tumor status.
8. Must have previously received at least 1 and no more than 2 lines of endocrine therapy, either as monotherapy or as a combination therapy with another agent.
9. Must have progressed during or within 28 days of completion of prior treatment with a CDK4/6 inhibitor in combination with either fulvestrant or an AI (this counts as a line of prior endocrine therapy).
10. Must have received no more than 1 line of cytotoxic chemotherapy in the advanced/metastatic setting.
11. Must have ctDNA ESR1-mut or ESR1-WT status as determined by central testing before subject is randomized.
12. ECOG performance status 0 or 1.

EXCLUSION CRITERIA

1. Prior treatment with elacestrant, GDC-0810, GDC-0927, GDC-9545, LSZ102, AZD9496, bazedoxifene, or other investigational SERD or investigational ER antagonist.
2. Prior anticancer or investigational drug treatment within the following windows:
   a. Fulvestrant treatment < 28 days before first dose of study drug.
   b. Any endocrine therapy < 14 days before first dose of study drug (with the exception of GnRH agonist therapy in male subjects).
   c. Chemotherapy < 21 days before first dose of study drug.
   d. Any investigational anti-cancer drug therapy < 28 days or five half-lives (whichever is shorter) before the first dose of study drug. Enrollment of subjects whose most recent therapy was an investigational agent should be discussed with the Sponsor.
3. Presence of symptomatic visceral disease as defined in protocol.
4. Diagnosis of any other malignancy within 5 years before enrollment.