

EMBER-3

TRIAL TITLE
A Study of Imlunestrant, Investigator's Choice of Endocrine Therapy, and Imlunestrant Plus Abemaciclib in Participants with ER+, HER2- Advanced Breast Cancer (EMBER-3)

TRIAL STATUS
Active, not recruiting

TRIAL NUMBER
NCT04975308

TRIAL PHASE
Phase 3

ABOUT THE EMBER-3 TRIAL:

- EMBER-3 is a phase 3 clinical trial evaluating imlunestrant (brand name: Inluriyo®), an oral selective estrogen receptor degrader (SERD) that blocks and destroys estrogen receptors, helping slow the growth of breast cancer cells.
- The trial enrolled people with ER-positive (ER+), HER2-negative (HER2-) advanced breast cancer whose disease had progressed on endocrine (hormone) therapy.
- Participants received either:
  - Imlunestrant alone
  - Standard hormone therapy
  - Imlunestrant combined with abemaciclib (brand name: Verzenio®)
- Findings from EMBER-3 led to FDA approvals of imlunestrant, either alone or with abemaciclib for eligible patients with *ESR1* mutation.

Clinical trials can be confusing. To learn more about them and some common terms check out this page.

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Breast Cancer Breakthroughs
FACT SHEET

3 KEY TAKEAWAYS FROM EMBER-3:

- **Improved outcomes:** Imlunestrant delayed cancer progression in patients compared to standard of care.
- **FDA approvals:** EMBER-3 results led to FDA approvals of imlunestrant with and without abemaciclib for people with ER+, HER2- advanced breast cancer with an *ESR1*-mutation.
- **Manageable side effects:** Most commonly joint or muscle pain, fatigue, diarrhea and nausea with imlunestrant monotherapy.

KEY BREAKTHROUGHS FROM EMBER-3:

- Imlunestrant helped delay cancer progression compared with standard hormone therapy in patients with *ESR1*-mutated, ER+, HER2- advanced breast cancer.
- The study showed that participants receiving imlunestrant lived slightly longer than those receiving standard hormone therapy, although the difference did not reach statistical significance.
- Combining imlunestrant with abemaciclib improved outcomes further and approximately doubled progression-free survival compared with imlunestrant alone.
- The trial showed the importance of *ESR1* mutation testing and biomarker-guided treatment approaches in advanced breast cancer.

SIDE EFFECTS AND QUALITY OF LIFE:

- Common side effects of imlunestrant may include joint or muscle pain, fatigue, diarrhea and nausea.
- Most side effects can be managed with support from a health care team. Patients should tell their health care team about any new or worsening symptoms.
- In EMBER-3, participants generally reported maintaining their quality of life while receiving treatment.

WHAT OUR MBC STEERING COMMITTEE SAYS ABOUT THE TRIAL RESULTS:

- Longer survival is a meaningful outcome for people living with metastatic breast cancer, noting that an improvement of >11 months could make a real difference.
- A new oral treatment option may help some patients delay the need for chemotherapy and avoid infusion visits.
- Quality of life and side effects remain important considerations when making treatment decisions.
- *ESR1* gene mutation testing can help patients and health care teams identify appropriate treatment options.
- Access, affordability, insurance coverage and patient self-advocacy remain important factors in making sure eligible patients can benefit from new treatments.

References:

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