



TBCRC-068

TRIAL TITLE

A Single Arm Phase II Trial of Circulating Tumor DNA-guided Adjuvant Therapy with Elacestrant in Adults with Hormone Receptor-Positive HER2-Negative Breast Cancers at Risk for Late Recurrence (TBCRC-068)

TRIAL STATUS

Recruiting

TRIAL NUMBER

[NCT06923527](https://clinicaltrials.gov/ct2/show/study/NCT06923527)

TRIAL PHASE

Phase 2

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Adults (women and men) diagnosed with hormone receptor-positive (ER-positive), HER2-negative early breast cancer with no known metastatic disease.
- Diagnosed at least 5 years ago but no more than 20 years ago and have completed adjuvant endocrine (hormone) therapy.
- Must be off endocrine therapy for at least four weeks before screening.
- No prior treatment with elacestrant or other investigational selective estrogen receptor degraders (SERDs).
- Have a positive circulating tumor DNA (ctDNA) result using the NEXT Personal assay.
- No clinical or radiologic evidence of cancer recurrence at the time of screening.

*Additional eligibility criteria may apply.

Spotlight on Clinical Trials FACT SHEET

TRIAL DETAILS:

- TBCRC-068 is a single-arm, phase 2 clinical trial evaluating a ctDNA-guided adjuvant treatment approach for ER+, HER2- breast cancer.
- The study plans to enroll approximately 50 participants.
- All participants who test positive for ctDNA during screening will receive elacestrant, taken orally once daily (345 mg) for 12 months, following the FDA-approved dosing schedule.
- The goal of the study is to determine whether starting elacestrant early after a positive ctDNA result can help reduce the risk of breast cancer returning (recurrence).
- Participants will undergo ctDNA testing and CT scans every 3 months during the first year of treatment.
- After the initial year, they will continue ctDNA testing every 6 months for one additional year.
- Participants who remain ctDNA-positive after 12 months may choose to continue elacestrant for up to one more year.

ABOUT ER+/HER2- BREAST CANCER AND ELACESTRANT:

- ER+, HER2- breast cancer is the most common breast cancer. Many patients benefit from treatments that lower estrogen (hormone) levels or block estrogen's effects on cancer cells.
- Even after completing standard treatments, some patients remain at risk for cancer recurrence. Researchers are studying new tools, such as ctDNA testing, to help identify who may be at higher risk and whether additional treatment could help.
- Elacestrant (brand name: Orserdu) is an oral SERD. It works by attaching to the estrogen receptor on cancer cells and limiting the receptor's activity, making it harder for the cancer to grow.
- Elacestrant is FDA-approved for certain patients with metastatic ER+, HER2- breast cancers that have an *ESR1* mutation, and is now being studied in earlier stage breast cancer in people who show signs of possible recurrence through ctDNA testing.
- Common side effects may include nausea, fatigue, decreased appetite, muscle or joint aches, diarrhea or constipation, hot flashes, and changes in cholesterol levels.

References:

1. Susan G. Komen. *Hormone Therapies*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/treatment/type/hormone-therapy/>
2. Susan G. Komen. *Tumor Characteristics*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/diagnosis/factors-that-affect-prognosis/tumor-characteristics/>
3. Susan G. Komen. *Selective Estrogen Receptor Degraders (SERDs) for Metastatic Breast Cancer*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/metastatic/metastatic/serds-for-metastatic-breast-cancer/>
4. Rozenblit, M. Circulating Tumor DNA. <https://clinicaltrials.gov/study/NCT06923527?cond=NCT06923527&rank=1>

Clinical trials can be confusing. To learn more about them and some common terms check out this [page](#).

