Spotlight on Clinical Trials

FACT SHEET

EmpowHER-303

TRIAL TITLE

A Study Comparing the Efficacy and Safety of Zanidatamab to Trastuzumab, Each in Combination with Physician's Choice Chemotherapy, for the Treatment of Participants with Metastatic HER2-positive Breast Cancer

TRIAL STATUS

Recruiting

TRIAL NUMBER

NCT06435429

TRIAL PHASE

Phase 3

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Adults aged 18+ with confirmed HER2-positive unresectable or metastatic breast cancer.
- Progressed on or intolerant to prior trastuzumab deruxtecan (T-DXd).
- Received at least 2 but not more than 4 prior lines of HER2-targeted therapies for HER2+ mBC.
- Adequate organ function:
  - Heart function (LVEF ≥50% via ECHO/MUGA).
  - Kidney function (creatinine clearance ≥30 mL/min).
- Stable or treated brain metastases.
- Not pregnant/breastfeeding + use of highly effective contraception if child-bearing.
- Life expectancy ≥6 months (per investigator judgment).

*Additional eligibility criteria may apply.

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TRIAL DETAILS:

- Approximately 550 participants randomized into two groups:
  - **Group 1:** Zanidatamab (a bispecific HER2-targeted antibody) + physician's choice of chemotherapy.
  - **Group 2:** Trastuzumab + physician's choice of chemotherapy (standard of care).
- Treatment continues until disease progression, unacceptable toxicity, or participant withdrawal.
- Evaluations include imaging (CT/MRI) every 6 weeks for the first 2 years, then every 9 weeks until progression
- Continuous monitoring of blood tests, alongside physical exams for safety assessment while participating in the trial.
- Researchers are testing if zanidatamab improves progression-free survival (the length of time people live without progression of their cancer or death) compared to the standard of care for people with metastatic HER2-positive breast cancer.

ABOUT HER2-POSITIVE METASTATIC BREAST CANCER AND ZANIDATAMAB:

- HER2-positive breast cancer is characterized by overexpression of the HER2 protein, which promotes cancer cell growth.
- This trial aims to determine if zanidatamab + chemotherapy improves clinical outcomes of patients with HER2+ mBC compared to standard of care trastuzumab + chemotherapy.
- Zanidatamab is an investigational bispecific antibody that targets two distinct parts of the HER2 protein, potentially enhancing efficacy over trastuzumab via enhanced anti-tumor activity.
- Zanidatamab is FDA-approved to treat HER2-positive IHC3+ biliary tract cancers.

REFERENCES:

1. ClinicalTrials.gov. A Study Comparing the Efficacy and Safety of Zanidatamab to Trastuzumab, Each in Combination with Physician's Choice Chemotherapy, for the Treatment of Participants with Metastatic HER2-positive Breast Cancer. Identifier: NCT06435429. Updated April 8, 2025. Accessed April 14, 2025. Available at: https://clinicaltrials.gov/study/NCT06435429