

BREAST CANCER

Breakthroughs Fact Sheet



HER2CLIMB-05

TRIAL TITLE: A Study of Tucatinib or Placebo with Trastuzumab and Pertuzumab for Metastatic HER2+ Breast Cancer (HER2CLIMB-05)

TRIAL STATUS: Recruiting

TRIAL NUMBER: [NCT05132582](https://clinicaltrials.gov/ct2/show/study/NCT05132582)

TRIAL PHASE: Phase III (Phase 3)

TRIAL DETAILS:

- Participants will be randomly assigned to 1 of 2 groups.
- Participants in one group will get the standard of care plus tucatinib (Tukysa), the test drug. Participants in the other group will get the standard of care plus the placebo (a pill that looks like the test drug but does not contain the medicine).
- These groups will continue their treatment until their cancer progresses (gets worse).
- Tucatinib and the placebo are pills taken by mouth 2 times a day. Trastuzumab and pertuzumab are given by IV (infusion) once every 3 weeks.
- Researchers are testing to see if including the test drug, tucatinib, in first-line maintenance therapy for metastatic HER2-positive breast cancer improves progression-free survival (the length of time people live without their cancer progressing) compared to the standard regimen of trastuzumab and pertuzumab alone.

ELIGIBLE PATIENTS:

- 18 years of age or older
- Diagnosed with advanced HER2-positive breast cancer.
- Have received or are receiving 4-8 cycles of standard first-line therapy with a taxane (chemotherapy), trastuzumab and pertuzumab.
- Participants with stable brain metastases are eligible.

ABOUT ADVANCED HER2-POSITIVE BREAST CANCER AND TUCATINIB:

- The current first-line therapy for metastatic HER2-positive breast cancer is 4-8 cycles of a taxane, trastuzumab and pertuzumab. Then participants are given maintenance therapy consisting of trastuzumab and pertuzumab.¹
- When the cancer progresses, trastuzumab-deruxtecan (Enhertu) is typically given as the second-line therapy.²
- Tucatinib is FDA approved in combination with trastuzumab and capecitabine (chemotherapy) for advanced HER2-positive breast cancer if the patient has received 2 or more prior lines of therapy.³
- Tucatinib has been found to delay progression of brain metastasis.⁴
- The most common side effects of tucatinib are diarrhea, nausea, fatigue, vomiting, and hand-foot syndrome.⁴

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REFERENCES:

1. Swain S.M. et al. Pertuzumab, Trastuzumab, and Docetaxel in Her2-Positive Metastatic Breast Cancer. New England Journal of Medicine. 2015. DOI: 10.1056/NEJMoa1413513
2. Cortes J. et al. Trastuzumab Deruxtecan versus Trastuzumab Emtansine for Breast Cancer. New England Journal of Medicine. 2022. DOI: 10.1056/NEJMoa2115022
3. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tucatinib-patients-her2-positive-metastatic-breast-cancer>
4. Murthy R.K. et al. Tucatinib, Trastuzumab, and Capecitabine for Her2-Positive Metastatic Breast Cancer. New England Journal of Medicine. 2020. DOI: 10.1056/NEJMoa1914609

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