

BREAST CANCER

Breakthroughs Fact Sheet



/// TROPION-Breast02

TRIAL TITLE: A Study of Dato-DXd Versus Investigator's Choice Chemotherapy in Patients with Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer, Who Are Not Candidates for PD-1/PD-L1 Inhibitor Therapy

TRIAL STATUS: Recruiting

TRIAL NUMBER: [NCT05374512](#)

TRIAL PHASE: Phase III (Phase 3)

TRIAL DETAILS:

- Participants will be randomized to receive a new antibody drug conjugate called datopotamab deruxtecan or Dato-DXd (not yet FDA approved) or the physician's choice of chemotherapy.
- The treatment will be administered through I.V. every three weeks until the cancer progresses.
- Researchers will determine if Dato-DXd improves progression-free survival compared to chemotherapy.

ELIGIBLE PATIENTS:

- 18 years of age or older
- Diagnosed with triple negative breast cancer (TNBC) that is locally recurrent and inoperable or metastatic.
- Have not received therapy for metastatic breast cancer.
- May not be a candidate for immunotherapy.

ABOUT TNBC AND DATO-DXD:

- The current first line of therapy for metastatic TNBC is chemotherapy or immunotherapy plus chemotherapy, but only about 40% of patients are eligible for immunotherapy.¹
- Dato-DXd is an antibody-drug conjugate that targets the TROP2 protein on cancer cells.
- Triple negative breast cancer cells have high levels of TROP2.²
- Phase 1 studies of Dato-DXd in TNBC found that 32% of patients responded to the drug.³
- The most common side effects of Dato-DXd are stomatitis, nausea, vomiting, fatigue, and alopecia.³

REFERENCES:

1. Cortes J. et al. Pembrolizumab plus chemotherapy in advanced triple-negative breast cancer. *New England Journal of Medicine*. 2022. DOI: 10.1056/NEJMoa2202809
2. Aslan M. et al. Oncogene-mediated metabolic gene signature predicts breast cancer outcome. *NPJ Breast Cancer*. 2021. DOI: 10.1038/s41523-021-00341-6
3. Bardia A. et al. Abstract P6-10-03: Datopotamab Deruxtecan (Dato-DXd) in advanced triple-negative breast cancer (TNBC): Updated results from the Phase 1 TROPION-PanTumor01 Study. *Proceedings of the 2022 San Antonio Breast Cancer Symposium*; 2022. Abstract number P6-10-03.

For more information, go to
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