



## TROPION-Breast05

### TRIAL TITLE

A Phase III Study of Dato-DXd With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy in Combination with Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer

### TRIAL STATUS

Recruiting

### TRIAL NUMBER

[NCT06103864](https://clinicaltrials.gov/study/NCT06103864)

### TRIAL PHASE

Phase 3

### PARTICIPANTS ELIGIBLE FOR THE STUDY\*:

- Adults with PD-L1-positive metastatic triple-negative breast cancer (TNBC).
- Have not had prior chemotherapy or antibody-drug conjugates (ADCs) for metastatic breast cancer (MBC).
- Must not have known active or untreated brain metastases.
- Must not have a history of leptomeningeal carcinomatosis or cancer that has spread to the leptomeninges.
- Must provide a tumor tissue sample from a recent or archived biopsy.

\*Additional eligibility criteria may apply.

## Spotlight on Clinical Trials FACT SHEET

### TRIAL DETAILS:

- This is a global, randomized, open-label, 3-arm Phase 3 study.
- The trial compares the safety and effectiveness of Dato-DXd with or without durvalumab against the investigator's choice of chemotherapy (ICC) in combination with pembrolizumab – the current standard of care.
- Participants will be randomly assigned to one of the treatment arms:
  - Dato-DXd
  - Dato-DXd plus durvalumab
  - ICC plus pembrolizumab
- Researchers will determine if the study treatment improves progression-free survival, or the time until the cancer progresses, compared to the current standard of care.

### ABOUT TRIPLE-NEGATIVE BREAST CANCER (TNBC) AND DATO-DXD:

- [TNBC](#) is an aggressive form of breast cancer that does not express estrogen receptors, progesterone receptors or HER2.
- This lack of receptor expression limits treatment options compared to other breast cancer types.
- Dato-DXd is an investigational antibody-drug conjugate (ADC) that targets TROP2, a protein often found on TNBC cells.
- People with metastatic PD-L1-positive TNBC are currently treated with pembrolizumab (an immunotherapy) combined with chemotherapy.
- The TROPION-Breast05 trial is testing whether Dato-DXd, alone or with durvalumab (an immunotherapy), can improve outcomes for people with PD-L1 positive TNBC.

### References:

1. NCT06103864. A Phase III Study of Dato-DXd With or Without Durvalumab Compared With Investigator's Choice of Chemotherapy in Combination With Pembrolizumab in Patients With PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer. ClinicalTrials.gov Identifier NCT06103864. Accessed June 25, 2025. <https://clinicaltrials.gov/study/NCT06103864#study-overview>
2. Triple Negative Breast Cancer: <https://www.komen.org/breast-cancer/diagnosis/triple-negative/>
3. Immunotherapy: <https://www.komen.org/breast-cancer/treatment/type/immunotherapy/>
4. Immunotherapy for MBC: <https://www.komen.org/breast-cancer/metastatic/metastatic/immunotherapy-for-metastatic-breast-cancer/>