TRIAL CARD

DESTINY-Breast04

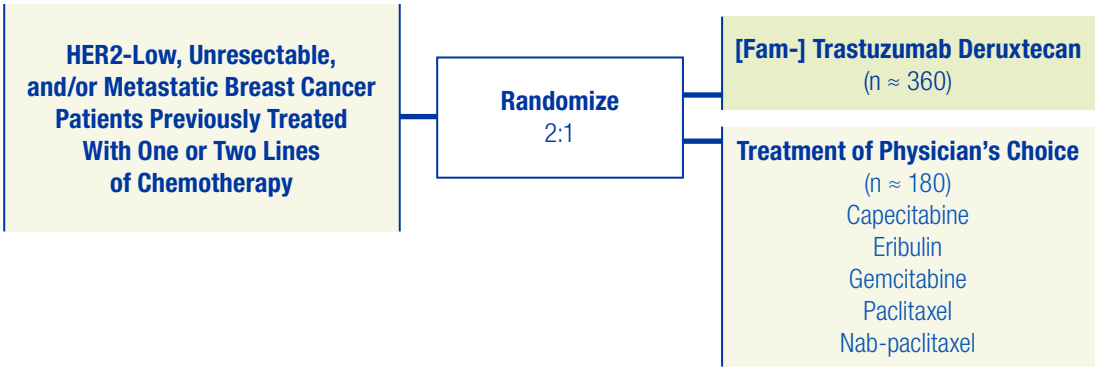
NOW ENROLLING
in the United States, Europe, and Japan

[Fam-] Trastuzumab Deruxtecan in Human Epidermal Growth Factor Receptor 2 (HER2)-Low Breast Cancer

Study description:

A phase 3, multicenter, randomized, open-label, active-controlled trial of [fam-] trastuzumab deruxtecan,* an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician's choice for HER2-low, unresectable and/or metastatic breast cancer patients.

Study design:



Primary endpoint:

Progression-free survival (PFS), based on blinded independent central review (BICR)

Key secondary endpoints:

- PFS, based on investigator assessment
- Overall survival (OS)
- Confirmed objective response rate (ORR)
- Duration of response (DoR)

[Fam-] trastuzumab deruxtecan is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established.

See reverse side for key enrollment criteria.

*[fam-] trastuzumab deruxtecan in US only; trastuzumab deruxtecan in other regions of world.

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Key inclusion criteria:

1. Is the age of majority in their country
2. Documented pathological breast cancer that is unresectable or metastatic, has low HER2 expression defined as IHC 2+/ISH- or IHC 1+ (ISH- or untested), and is HR-positive or HR-negative
3. Has progressed on, and would no longer benefit from, endocrine therapy, and previously treated with 1 to 2 prior lines of chemotherapy/adjuvant in the metastatic setting
4. At least one measurable lesion per modified Response Evaluation Criteria in Solid Tumors (mRECIST) version 1.1
5. Protocol-defined adequate cardiac, bone marrow, renal, hepatic and blood clotting function

Key exclusion criteria:

1. Ineligible for all 5 of the options in the investigator's choice arm
2. Has previously been treated with any anti-HER2 therapy, including an antibody drug conjugate
3. Uncontrolled or significant cardiovascular disease
4. Medical history of clinically significant interstitial lung disease (ILD)/pneumonitis or is suspected to have ILD/pneumonitis based on imaging at screening period
5. Spinal cord compression or clinically active central nervous system metastases

Location: Study sites in North America, Western Europe, and Asia

For more information please visit: https://clinicaltrials.gov/ct2/show/study/NCT03734029.

ClinicalTrials.gov identifier: NCT03734029, EUDRA clinical trials identifier: 2018-003069-33, Japan clinical trials identifier: JapicCTI-184223

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