ForPatients
by Roche

Breast Cancer

A Study of Trastuzumab Emtansine in Participants With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer Who Have Received Prior Anti-HER2 And Chemotherapy-based Treatment

Trial Status	Trial Runs In	Trial Identifier
Completed	44 Countries	NCT01702571 2012-001628-37 MO28231

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Two-Cohort, Open-Label, Multicenter Study of Trastuzumab Emtansine (T-DM1) in HER2-Positive Locally Advanced or Metastatic Breast Cancer Patients Who Have Received Prior Anti-HER2 and Chemotherapy-Based Treatment

Trial Summary:

This two-cohort, open-label, multicenter study will assess the safety, efficacy and tolerability of trastuzumab emtansine in participants with HER2-positive locally advanced breast cancer (LABC) or metastatic breast cancer (mBC) who have received prior anti-HER2 and chemotherapy-based treatment. Participants in Cohort 1 will be drawn from the general participant population; Cohort 2 will include only Asian participants.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT01702571 2012-001628-37 MO28231
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- HER2-positive disease determined locally
- Histologically or cytologically confirmed invasive breast cancer
- Prior treatment for breast cancer in the adjuvant, unresectable, locally advanced or metastatic setting must include both chemotherapy, alone or in combination with another agent, and an anti-HER2 agent, alone or in combination with another agent
- Documented progression of incurable, unresectable, LABC, or mBC, defined by the investigator: progression must occur during or after most recent treatment for LABC/mBC or within 6 months of completing adjuvant therapy
- Measurable and/or non-measurable disease
- Left ventricular ejection fraction (LVEF) >/=50% by either echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0,1 or 2
- Adequate organ function
- Use of highly effective contraception as defined by the protocol

Exclusion Criteria:

- History of treatment with trastuzumab emtansine
- Prior enrollment into a clinical study containing trastuzumab emtansine regardless of having received trastuzumab emtansine or not
- Peripheral neuropathy of Grade >/= 3 per National Cancer Institute (NCI) common terminology criteria for adverse events (CTCAE) v 4.0
- History of other malignancy within the previous 5 years, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, Stage 1 uterine cancer, synchronous or previously diagnosed HER2-positive breast cancer
- History of receiving any anti-cancer drug/biologic or investigational treatment within 21 days prior to first study treatment except hormone therapy, which can be given up to 7 days prior to first study treatment; recovery of treatment-related toxicity consistent with other eligibility criteria
- History of exposure to cumulative doses of anthracyclines
- History of radiation therapy within 14 days of first study treatment. The participant must have recovered from any resulting acute toxicity (to Grade </=1) prior to first study treatment.
- Metastatic central nervous system (CNS) disease only
- Brain metastases which are symptomatic
- History of a decrease in LVEF to less than (<) 40% or symptomatic congestive heart failure (CHF) with previous trastuzumab treatment
- History of symptomatic CHF (New York Heart Association [NYHA] Classes II-IV) or serious cardiac arrhythmia requiring treatment
- History of myocardial infarction or unstable angina within 6 months of first study treatment
- Current dyspnea at rest due to complications of advanced malignancy or requirement for continuous oxygen therapy
- Current severe, uncontrolled systemic disease (clinically significant cardiovascular, pulmonary, or metabolic disease)
- Pregnancy or lactation
- Currently known active infection with human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus
- History of intolerance (such as Grade 3-4 infusion reaction) or hypersensitivity to trastuzumab or murine proteins or any component of the product