ForPatients
by Roche

Breast Cancer

Efficacy and Safety of Trastuzumab Emtansine in Chinese Participants With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Locally Advanced or Metastatic Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03084939 BO29919

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 Randomized, Multicenter, Phase III Open-Label Study of the Efficacy and Safety of Trastuzumab Emtansine Versus Lapatinib Plus Capecitabine in Chinese Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer Who Have Received Prior Trastuzumab-Based Therapy

Trial Summary:

This is a Phase III, randomized, multicenter, two-arm, open-label study designed to evaluate the safety and efficacy of trastuzumab emtansine compared with that of lapatinib + capecitabine in Chinese participants with HER2-positive, unresectable locally advanced breast cancer (LABC) or metastatic breast cancer (MBC) who have received prior trastuzumab-based therapy. A total of approximately 350 participants will be enrolled in China. The study will consist of 2 stages. Stage 1: Eligible participants will be randomized in a 3:1 ratio to receive either trastuzumab emtansine or control (lapatinib + capecitabine). Stage 2: After Stage 1 is recruited, eligible patients will be enrolled to receive trastuzumab emtansine only.

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

NCT03084939 BO29919
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Aged >/= 18 years
- Prospective centrally assessed HER2-positive disease (i.e., immunohistochemistry [IHC] 3+ and/or gene amplified [HER2 to Chromosome 17 [CEP 17] ratio >/= 2]) by in situ hybridization (ISH) through use of archival paraffin-embedded tumor tissue
- Histologically or cytologically confirmed invasive breast cancer (BC): incurable, unresectable LABC previously treated with multimodality therapy or MBC
- Prior treatment for BC in the adjuvant, unresectable locally advanced or metastatic setting must include both: a taxane, alone or in combination with another agent, and trastuzumab, alone or in combination with another agent in the adjuvant, unresectable locally advanced or metastatic setting
- Documented progression of incurable, unresectable LABC or MBC, defined by the investigator: progression must occur during or after most recent treatment for LABC or MBC or within 6 months after completing adjuvant therapy
- Measurable and/or non-measurable disease, according the Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 definition: CNS-only disease excluded
- Left ventricular ejection fraction (LVEF) >/=50% by either echocardiogram or multiple-gated acquisition
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Adequate organ function evidenced by laboratory results within 30 days prior to randomization
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use non-hormonal contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 7 months after the last dose of study drug
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures (use a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year) and agreement to refrain from donating sperm during the treatment period and for at least 7 months after the last dose of study drug

Exclusion Criteria:

- History of treatment with trastuzumab emtansine
- Prior treatment with lapatinib or capecitabine
- Peripheral neuropathy of Grade >/= 3 per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI CTCAE v4.0)
- 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 BC, or cancers with a similar curative outcome as those mentioned above
- History of receiving any anti-cancer drug/biologic or investigational treatment within 21 days prior to randomization, except hormone therapy which can be given up to 7 days prior to randomization
- History of radiation therapy within 14 days before randomization
- Brain metastases that are untreated, symptomatic, progressive, or require therapy such as radiation, surgery or corticosteroid therapy to control symptoms from brain metastases within 30 days before randomization
- History of exposure to cumulative doses of anthracyclines: Doxorubicin > 500 milligrams per square meter (mg/m^2), Epirubucin > 720 mg/m^2, Mitoxantrone > 120 mg/m^2
- Current severe, uncontrolled systemic disease (e.g., clinically significant cardiovascular, pulmonary, or metabolic disease)
- Pregnancy or lactation
- Currently known active infection with HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV)
- Presence of conditions that could affect gastrointestinal absorption
- History of intolerance (including Grade 3 or 4 infusion reaction) or hypersensitivity to trastuzumab or murine proteins

- Known hypersensitivity to 5-fluorouracil or known dihydropyrimidine dehydrogenase deficiency
- Current treatment with sorivudine or its chemically related analogs