ForPatients
by Roche

Breast Cancer

A Study to Evaluate the Efficacy and Safety of Pertuzumab + Trastuzumab + Docetaxel Versus Placebo + Trastuzumab + Docetaxel in Previously Untreated Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Metastatic Breast Cancer (MBC)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02896855 YO29296

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 Phase III, Randomized, Double-blind, Placebo-controlled Clinical Trial to Evaluate the Efficacy and Safety of Pertuzumab+Herceptin+Docetaxel Versus Placebo+Herceptin+Docetaxel in Previously Untreated HER2-Positive Metastatic Breast Cancer

Trial Summary:

This Phase III, randomized, double-blind, placebo-controlled, multicenter clinical trial in China will evaluate the efficacy and safety of pertuzumab + trastuzumab + docetaxel compared with placebo + trastuzumab + docetaxel in participants with previously untreated HER2-positive metastatic breast cancer.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02896855 YO29296
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of the breast with locally recurrent or metastatic disease that is suitable for chemotherapy

- HER2-positive metastatic breast cancer (MBC)
- Left ventricular ejection fraction (LVEF) greater than or equal to (>=) 55 percent (%) at baseline (within 42 days of randomization)
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Women of childbearing potential and men should agree to use an effective form of contraception and to continue its use for the duration of study treatment and for at least 7 months after the last dose of study treatment (trastuzumab and/or pertuzumab)

Exclusion Criteria:

- History of anti-cancer therapy for MBC (with the exception of one prior hormonal regimen for MBC)
- History of approved or investigative tyrosine kinase/HER inhibitors for breast cancer in any treatment setting, except trastuzumab used in the neoadjuvant or adjuvant setting
- History of systemic breast cancer treatment in the neo-adjuvant or adjuvant setting with a disease-free interval from completion of the systemic treatment (excluding hormonal therapy) to metastatic diagnosis of less than (<) 12 months
- History of persistent Grade >= 2 hematologic toxicity resulting from previous adjuvant therapy
- Grade >= 3 peripheral neuropathy at randomization
- History of other malignancy within the last 5 years, except for carcinoma in situ of the cervix or non-melanoma skin carcinoma that has been previously treated with curative intent
- Current clinical or radiographic evidence of central nervous system (CNS) metastases
- History of exposure to cumulative doses of anthracyclines
- Current uncontrolled hypertension or unstable angina
- History of congestive heart failure (CHF) of any New York Heart Association (NYHA) classification, or serious cardiac arrhythmia requiring treatment
- History of myocardial infarction within 6 months of randomization
- History of LVEF decrease to < 50% during or after prior trastuzumab neo-adjuvant or adjuvant therapy
- Current dyspnea at rest due to complications of advanced malignancy, or other diseases that require continuous oxygen therapy
- Inadequate organ function within 28 days prior to randomization
- Current severe, uncontrolled systemic disease
- Major surgical procedure or significant traumatic injury within 28 days prior to study treatment start or anticipation of the need for major surgery during the course of study treatment
- Pregnant or lactating women
- History of receiving any investigational treatment within 28 days of randomization
- Current known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or active hepatitis B virus (HBV)
- Receipt of intravenous (IV) antibiotics for infection within 14 days of randomization
- Current chronic daily treatment with corticosteroids (excluding inhaled steroids)
- Known hypersensitivity to any of the protocol-specified study treatments
- Concurrent participation in an interventional or noninterventional study