ForPatients
by Roche

Breast Cancer HER-2 PositiveHER2-positive Early Breast CancerBreast CancerHER2-Positive Breast Cancer

A Two-Arm Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Combination With Chemotherapy in Chinese Participants With HER2-Positive Early Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT04024462 YO41137

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, Multicenter, Open-Label, Two-Arm Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Combination With Chemotherapy in Chinese Patients With HER2-Positive Early Breast Cancer

Trial Summary:

This study will evaluate the pharmacokinetics, efficacy, and safety of the pertuzumab and trastuzumab fixed-dose combination for subcutaneous administration (PH FDC SC) as compared with those of the pertuzumab intravenous (IV) and trastuzumab IV formulations in Chinese participants with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer.

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

NCT04024462 YO41137
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Ability to comply with the study protocol, in the investigator's judgment
- Eastern Cooperative Oncology Group (ECOG) Performance Status greater or equal to (#)1
- Stage II-IIIC (T2-T4 plus any N, or any T plus N1-3, M0), locally advanced, inflammatory, or early-stage, unilateral, and histologically confirmed invasive breast cancer
- Primary tumor greater than (>)2 centimeters (cm) in diameter, or node-positive disease (clinically or on imaging, and node positivity confirmed with cytology and/or histopathology)
- Human Epidermal Growth Factor Receptor 2 (HER2)-positive breast cancer confirmed by a central laboratory prior to study enrollment. HER2-positive status will be determined based on pretreatment breast biopsy material and defined as 3+ by immunohistochemistry (IHC) and/or positive by HER2 amplification by in situ hybridization (ISH) with a ratio of #2 for the number of HER2 gene copies to the number of signals for chromosome 17 copies
- Hormone receptor status of the primary tumor, centrally confirmed
- Patient agreement to undergo mastectomy or breast conserving surgery after neoadjuvant therapy
- Availability of formalin-fixed, paraffin-embedded (FFPE) tumor tissue for central confirmation of HER2, hormone receptor status, and PIK3CA mutational analyses
- Baseline left ventricular ejection fraction (LVEF) #55% measured by echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA)
- For women of childbearing potential (WOCBP) who are sexually active: agreement to remain abstinent (refrain from heterosexual intercourse) or use one highly effective non-hormonal contraceptive method with a failure rate of less than (<)1% per year, or two effective non-hormonal contraceptive methods during the treatment period and for 7 months after the last dose of HER2-targeted therapy, and agreement to refrain from donating eggs during this same period
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom in combination with a spermicidal foam, gel, film, cream, or suppository, and agreement to refrain from donating sperm, as specified in the protocol
- A negative serum pregnancy test must be available prior to randomization for WOCBP (premenopausal women and women <12 months after the onset of menopause), unless they have undergone surgical sterilization (removal of ovaries and/or uterus)
- No major surgical procedure unrelated to breast cancer within 28 days prior to randomization or anticipation of the need for major surgery during the course of study treatment

Exclusion Criteria:

- Stage IV (metastatic) breast cancer
- History of invasive breast cancer
- History of concurrent or previously treated non-breast malignancies except for appropriately treated 1) non-melanoma skin cancer and/or 2) in situ carcinomas, including cervix, colon, and skin
- Have received any previous systemic therapy (including chemotherapy, immunotherapy, HER2-targeted agents, endocrine therapy [selective estrogen receptor modulators, aromatase inhibitors], and antitumor vaccines) for treatment or prevention of breast cancer, or radiation therapy for treatment of cancer
- Have a past history of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) if they have received any systemic therapy for its treatment or radiation therapy to the ipsilateral breast
- High-risk for breast cancer and have received chemopreventative drugs in the past
- Multicentric (multiple tumors involving more than one quadrant) breast cancer, unless all tumors are HER2-positive
- Bilateral breast cancer
- Have undergone an excisional biopsy of primary tumor and/or axillary lymph nodes
- Axillary lymph node dissection (ALND) prior to initiation of neoadjuvant therapy

- Sentinel lymph node biopsy (SLNB) prior to neoadjuvant therapy
- Treatment with any investigational drug within 28 days prior to randomization
- Serious cardiac illness or medical conditions
- Inadequate bone marrow function
- Impaired liver function
- Inadequate renal function with serum creatinine >1.5X upper limit of normal (ULN)
- Current severe, uncontrolled systemic disease that may interfere with planned treatment (e.g., clinically significant cardiovascular, pulmonary, or metabolic disease; wound-healing disorders)
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 7 months after the last dose of HER2-targeted therapy
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- Known active liver disease, for example, active viral hepatitis infection (i.e., hepatitis B or hepatitis C), autoimmune hepatic disorders, or sclerosing cholangitis
- Concurrent, serious, uncontrolled infections, or known infection with HIV
- Known hypersensitivity to study drugs, excipients, and/or murine proteins
- Current chronic daily treatment with corticosteroids (dose >10 milligrams [mg] methylprednisolone or equivalent excluding inhaled steroids)
- History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, colon, skin, and/or non-melanoma skin carcinoma
- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias, such as structural heart disease (e.g., severe LVSD, left ventricular hypertrophy), coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing), clinically significant electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia, hypocalcemia), or family history of sudden unexplained death or long QT syndrome