ForPatients
*by Roche*

Breast Cancer

# A Study Evaluating Pertuzumab (Perjeta) Combined With Trastuzumab (Herceptin) and Standard Anthracycline-based Chemotherapy in Participants With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Locally Advanced, Inflammatory, or Early-stage Breast Cancer

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 12 Countries | NCT02132949 2014-000156-28 WO29217 |

*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 Multicenter, Multinational, Phase II Study to Evaluate Perjeta in Combination With Herceptin and Standard Neoadjuvant Anthracycline-Based Chemotherapy in Patients With HER2-Positive, Locally Advanced, Inflammatory, or Early-Stage Breast Cancer

## *Trial Summary:*

This multicenter, non-randomized, open-label, phase 2 study is designed to evaluate the safety and efficacy of pertuzumab (Perjeta) in combination with trastuzumab (Herceptin) and anthracycline-based chemotherapy as neoadjuvant treatment in participants with HER2-positive locally advanced, inflammatory, or early-stage breast cancer. Each investigator will choose a treatment regimen (A or B) for all of their participants to follow. Treatment regimen A (for Cohort A) will include dose-dense doxorubicin and cyclophosphamide (ddAC), followed by paclitaxel, with pertuzumab and trastuzumab given from the start of paclitaxel. Treatment regimen B (for Cohort B) will include 5-fluorouracil, epirubicin, and cyclophosphamide (FEC), followed by docetaxel, with pertuzumab and trastuzumab given from the start of docetaxel. Participants in both cohorts will subsequently undergo surgical treatment and then resume pertuzumab and trastuzumab treatment.

| **Hoffmann-La Roche** | **Phase 2** |
|---|---|
| Sponsor | Phase |

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## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| **All** | **#18 Years** | **No** |

## *Inclusion Criteria:*

- Male and female participants with locally advanced, inflammatory, or early-stage, unilateral, and histologically confirmed invasive breast cancer. Participants with inflammatory breast cancer must be able to have a core needle biopsy
- Primary tumor greater than (>) 2 centimeters (cm) in diameter, or > 5 millimeters (mm) in diameter and node-positive
- HER2-positive breast cancer confirmed by a central laboratory
- Availability of tumor tissue specimen
- Baseline LVEF greater than or equal to (>/=) 55%
- Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to (</=) 1
- At least 4 weeks since major unrelated surgery, with full recovery
- Women of childbearing potential and male participants with partners of childbearing potential must agree to use a "highly effective" non-hormonal form of contraception or two "effective" forms of non-hormonal contraception by the patient and/or partner. Contraception must continue for the duration of study treatment and for at least 7 months after the last dose of study treatment

## *Exclusion Criteria:*

- Metastatic disease (Stage IV) or bilateral breast cancer
- Participants who have had an incisional biopsy of the primary tumor or the primary tumor excised
- Prior breast or non-breast malignancy within 5 years prior to study entry, except for carcinoma in situ and basal cell and squamous cell carcinoma of the skin. Participants with malignancies occurring more than 5 years prior to study entry are permitted if curatively treated
- Any previous systemic therapy (including chemotherapy, immunotherapy, HER2 targeted agents, and antitumor vaccines) for cancer, or radiation therapy for cancer
- Participants with a past history of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) are not allowed to enter the study if they have received any systemic therapy for its treatment or radiation therapy to the ipsilateral breast (they are allowed to enter the study if treated with surgery alone)
- High-risk participants who have received chemopreventive drugs in the past are not allowed to enter the study
- Inadequate bone marrow, renal, or liver function
- History or evidence of cardiovascular condition
- Dyspnea at rest or other diseases that require continuous oxygen therapy
- Severe, uncontrolled systemic disease
- Participants with poorly controlled diabetes or with evidence of clinically significant diabetic vascular complications
- Pregnancy or breast-feeding women
- Participants who received any investigational treatment within 4 weeks of study start
- Participants with known infection with human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus
- Current chronic daily treatment with corticosteroids (dose >10 mg methylprednisolone or equivalent [excluding inhaled steroids])
- Known hypersensitivity to any of the study drugs or excipients

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