ForPatients
by Roche

Breast Cancer

A Study of Trastuzumab Emtansine (Kadcyla) Plus Pertuzumab (Perjeta) Following Anthracyclines in Comparison With Trastuzumab (Herceptin) Plus Pertuzumab and a Taxane Following Anthracyclines as Adjuvant Therapy in Participants With Operable HER2-Positive Primary Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	36 Countries	NCT01966471 2012-004902-82 BO28407

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, Open-Label, Phase III Trial Comparing Trastuzumab Plus Pertuzumab Plus a Taxane Following Anthracyclines Versus Trastuzumab Emtansine Plus Pertuzumab Following Anthracyclines as Adjuvant Therapy in Patients With Operable HER2-Positive Primary Breast Cancer

Trial Summary:

This two-arm, randomized, open-label, multicenter study will evaluate the efficacy and safety of trastuzumab emtansine in combination with pertuzumab versus trastuzumab in combination with pertuzumab and a taxane as adjuvant therapy in participants with human epidermal growth (HER) factor 2 (HER2)-positive primary invasive breast cancer. Following surgery and anthracycline-based chemotherapy, participants will receive either trastuzumab emtansine at a dose of 3.6 milligrams per kilogram (mg/kg) and pertuzumab at a dose of 420 milligrams (mg) intravenously (IV) every 3 weeks (q3w) or trastuzumab at a dose of 6 mg/kg and pertuzumab at a dose of 420 mg IV q3w in combination with a taxane.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT01966471 2012-004902-82 BO28407
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to (</=) 1
- Non-metastatic histologically confirmed primary invasive breast carcinoma that was operable
- HER2-positive breast cancer
- Known hormone receptor status of the primary tumor
- Adequately excised: participants must have undergone either breast-conserving surgery or mastectomy/nipple- or skin-sparing mastectomy
- Pathological tumor-node-metastasis staging (Union for International Cancer Control-American Joint Committee on Cancer [UICC/AJCC] 7th edition): eligible participants must have either:

Node-positive disease (pN more than or equal to [>/=] 1), any tumor size except T0, and any hormonal receptor status; or Node-negative disease (pN0) with pathologic tumor size >2.0 centimeters by standard local assessment and negative for estrogen receptor (ER) and progesterone receptor (PR) determined by a central pathology laboratory

- Participants with synchronous bilateral invasive disease are eligible only if both lesions are HER2-positive
- No more than 9 weeks (63 days) may elapse between definitive breast surgery (or the last surgery if additional resection required for breast cancer) and randomization
- Baseline left ventricular ejection fraction (LVEF) >/=55% measured by echocardiogram (ECHO; preferred) or multiple-gated acquisition (MUGA) scans
- Documentation on hepatitis B virus (HBV) and hepatitis C virus (HCV) serology is required
- Female participants of childbearing potential must be willing to use one highly effective form of non-hormonal contraception or two effective forms of non-hormonal contraception. For male participants with partners of childbearing potential, one highly effective form of contraception or two effective forms of contraception must be used. Contraception must continue for the duration of study treatment and for 6 months after the last dose of study treatment

Exclusion Criteria:

- History of any prior (ipsilateral and/or contralateral) invasive breast carcinoma
- History of non-breast malignancies within the 5 years prior to randomization, except for carcinoma in situ (CIS) of the cervix, CIS of the colon, melanoma in situ, and basal cell and squamous cell carcinomas of the skin
- Any clinical T4 tumor as defined by tumor-node-metastasis classification in UICC/AJCC 7th edition, including inflammatory breast cancer
- For the currently diagnosed breast cancer, any previous systemic anti-cancer treatment (for example, neoadjuvant or adjuvant), including but not limited to, chemotherapy, anti-HER2 therapy (for example, trastuzumab, trastuzumab emtansine, pertuzumab, lapatinib, neratinib, or other tyrosine kinase inhibitors), hormonal therapy, OR anti-cancer radiation therapy (RT) (intra-operative radiotherapy as a boost at the time of primary surgery is acceptable)
- Previous therapy with anthracyclines, taxanes, or HER2-targeted therapy for any malignancy
- History of DCIS and/or lobular CIS (LCIS) that was treated with any form of systemic chemotherapy, hormonal therapy, or RT to the ipsilateral breast where invasive cancer subsequently developed. Participants who had their DCIS/LCIS treated with surgery only and/or contralateral DCIS treated with radiation are allowed to enter the study

- Participants with contraindication to RT while adjuvant RT is clinically indicated
- Concurrent anti-cancer treatment in another investigational trial
- Cardiopulmonary dysfunction as defined by protocol: angina pectoris requiring anti-anginal medication, serious cardiac arrhythmia not controlled by adequate medication, severe conduction abnormality, or clinically significant valvular disease, significant symptoms (Grade >/=2) relating to left ventricular dysfunction, cardiac arrhythmia, or cardiac ischemia, myocardial infarction within 12 months prior to randomization, uncontrolled hypertension, evidence of transmural infarction on electrocardiogram (ECG), requirement for oxygen therapy
- Other concurrent serious diseases that may interfere with planned treatment, including severe pulmonary conditions/illness, uncontrolled infections, uncontrolled diabetes, or known infection with HIV
- Any known active liver disease. For participants who are known carriers of HBV/HCV, active hepatitis B/C infection must be ruled out per local guidelines
- Inadequate hematologic, renal or liver function
- Pregnant or lactating women
- Hypersensitivity to any of the study medications or any of the ingredients or excipients of these medications, including hypersensitivity to benzyl alcohol
- Chronic immunosuppressive therapies, including systemic corticosteroids