ForPatients
by Roche

Breast Cancer HER-2 PositiveBreast Neoplasms

A Study of Pertuzumab in Combination With Trastuzumab (Herceptin) and a Taxane in First-Line Treatment in Participants With Human Epidermal Growth Factor 2 (HER2)-Positive Advanced Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	39 Countries	NCT01572038 2011-005334-20 MO28047

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, Open-Label, Single-Arm Study of Pertuzumab in Combination With Trastuzumab and a Taxane in First Line Treatment of Patients With HER2-Positive Advanced (Metastatic or Locally Recurrent) Breast Cancer

Trial Summary:

This multicenter, open-label, single-arm, Phase IIIb study will evaluate the safety and tolerability of pertuzumab in combination with trastuzumab (Herceptin) and a taxane (docetaxel, paclitaxel or nab-paclitaxel) in first-line treatment in participants with metastatic or locally recurrent HER2-positive breast cancer. Participants will receive pertuzumab intravenously (IV) and trastuzumab (Herceptin) IV plus a taxane in cycles of 3 weeks each until predefined study end, unacceptable toxicity, withdrawal of consent, disease progression, or death, whichever occurs first.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT01572038 2011-005334-20 MO28047
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of the breast with metastatic or locally recurrent disease not amenable to curative resection
- HER2-positive breast cancer
- Eastern cooperative Oncology Group (ECOG) performance status 0, 1 or 2
- LVEF of at least 50 percent (%)

Exclusion Criteria:

- Previous systemic non-hormonal anti-cancer therapy for metastatic or locally recurrent disease
- Disease-free interval from completion of adjuvant or neoadjuvant systemic non-hormonal treatment to recurrence less than or equal to (</=) 6 months
- Previous approved or investigative anti-HER2 agents in any breast cancer treatment setting, except for trastuzumab and/or lapatinib in the adjuvant or neoadjuvant setting
- Disease progression while receiving trastuzumab and/or lapatinib in the adjuvant or neoadjuvant setting
- History of persistent Grade 2 or higher (National Cancer Institute Common Toxicity Criteria [NCI-CTC], Version 4.0) hematological toxicity resulting from previous adjuvant or neoadjuvant therapy
- Central nervous system (CNS) metastases
- Current peripheral neuropathy of Grade 3 or greater (NCI-CTC, version 4.0)
- History of other malignancy within the last 5 years prior to first study drug administration, except for carcinoma in situ of the cervix or basal cell carcinoma
- Inadequate bone marrow, liver or renal function
- Uncontrolled hypertension
- Hepatitis B, hepatitis C or Human Immunodeficiency Virus (HIV) infection