

Breast CancerMetastatic Breast Cancer

Pertuzumab With High-Dose Trastuzumab in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Metastatic Breast Cancer (MBC) With Central Nervous System (CNS) Progression Post-Radiotherapy

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
NCT02536339 ML29366

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:

An Open-Label, Single-Arm, Phase II Study of Pertuzumab With High-Dose Trastuzumab for the Treatment of Central Nervous System Progression Post-Radiotherapy in Patients With HER2-Positive Metastatic Breast Cancer (PATRICIA)

Trial Summary:

This study will examine the safety and efficacy of pertuzumab in combination with high-dose trastuzumab in adult participants with HER2-positive MBC with CNS metastases and disease progression in the brain following radiotherapy.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT02536339 ML29366
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Pathologically confirmed HER2-positive MBC
- Progression of or new brain metastases after completion of whole-brain radiotherapy or stereotactic radiosurgery

ForPatients

by Roche

- Completion of whole-brain radiotherapy or stereotactic radiosurgery more than 60 days prior to enrollment
- Stable systemic disease
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- LVEF at least 50%
- Adequate hematologic, renal, and hepatic function
- Life expectancy more than 12 weeks

Exclusion Criteria:

- Progression of systemic disease at Screening
- Leptomeningeal disease
- History of intolerance or hypersensitivity to study drug
- Use of certain investigational therapies within 21 days prior to enrollment
- Current anthracycline use
- Unwillingness to discontinue ado-trastuzumab emtansine or lapatinib use
- Active infection
- Pregnant or lactating women
- Significant history or risk of cardiac disease
- Symptomatic intrinsic lung disease or lung involvement
- History of other malignancy within the last 5 years