ForPatients
by Roche

Metastatic Breast CancerBreast Cancer

A Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine in Combination With Atezolizumab or Atezolizumab-Placebo in Participants With Human Epidermal Growth Factor-2 (HER2) Positive Locally Advanced or Metastatic Breast Cancer (BC) Who Received Prior Trastuzumab and Taxane Based Therapy

Trial Status	Trial Runs In	Trial Identifier
Completed	9 Countries	NCT02924883 2015-004189-27 WO30085

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, Double-Blind, Placebo-Controlled Phase II Study of the Efficacy and Safety of Trastuzumab Emtansine in Combination With Atezolizumab or Atezolizumab-Placebo in Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer Who Have Received Prior Trastuzumab and Taxane Based Therapy

Trial Summary:

This Phase II, double-blind, randomized, placebo-controlled multicenter study will investigate the efficacy and safety of trastuzumab emtansine in combination with atezolizumab or atezolizumab-placebo in participants with HER2-positive locally advanced or metastatic BC who have received prior trastuzumab and taxane based therapy, either alone or in combination, and/or who have progressed within 6 months after completing adjuvant therapy.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT02924883 2015-004189-27 WO30085
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Archival tumor samples must be obtained from primary and/or metastatic sites
- Able to submit tumor tissue that is evaluable for programmed death- ligand 1 (PD-L1) expression
- HER-2 positive BC as defined by an immunohistochemistry score of 3 or gene amplified by in-situ hybridization as defined by a ratio of greater than or equal to (>=) 2.0 for the number of HER2 gene copies to the number of chromosome 17 copies
- Histologically or cytologically confirmed invasive BC: incurable, unresectable, locally advanced BC previously treated with multimodality therapy or metastatic BC
- Prior treatment for BC in the: adjuvant; unresectable locally advanced; or metastatic settings; which must include both, a taxane and trastuzumab (alone or in combination with another agent)
- Progression must have occurred during or after most recent treatment for locally advanced/metastatic BC or within 6 months after completing adjuvant therapy
- Participants must have measurable disease that is evaluable as per RECIST v1.1
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Negative serum pregnancy test within 7 days of enrollment for pre-menopausal women and for women less than 12 months after the onset of menopause
- Use of highly effective method of contraception as defined by the protocol

Exclusion Criteria:

- Prior treatment with trastuzumab emtansine, cluster of differentiation 137 agonists, anti-programmed death-1, or anti-PD-L1 therapeutic antibody or pathway-targeting agents
- Receipt of any anti-cancer drug/biologic or investigational treatment within 21 days prior to Cycle 1 Day 1 except hormone therapy, which can be given up to 7 days prior to Cycle 1 Day 1; recovery of treatment related toxicity consistent with other eligibility criteria
- Radiation therapy within 2 weeks prior to Cycle 1, Day 1
- History of exposure to the cumulative doses of anthracyclines
- History of other malignancy within the previous 5 years, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, Stage I uterine cancer, or participants who have undergone potentially curative therapy with no evidence of disease and are deemed by the treating physician to be at low risk for recurrence
- Cardiopulmonary dysfunction, symptomatic pleural effusion, pericardial effusion, or ascites
- Participants with severe infection within 4 weeks prior to randomization, including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia
- Current severe, uncontrolled systemic disease
- Major surgical procedure or significant traumatic injury within 28 days prior to randomization or anticipation of the need for major surgery during the course of study treatment
- Clinically significant history of liver disease, including cirrhosis, current alcohol abuse, autoimmune hepatic disorders, sclerosis cholangitis or active infection with human immunodeficiency virus, hepatitis B virus, or hepatitis C virus
- Need for current chronic corticosteroid therapy (>=10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids)
- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for greater than (>) 2 weeks prior to randomization
- Participants with known central nervous system disease
- Leptomeningeal disease
- History of autoimmune disease
- Prior allogeneic stem cell or solid organ transplantation
- Active tuberculosis

- Receipt of a live, attenuated vaccine within 4 weeks prior to randomization or anticipation that such a live, attenuated vaccine will be required during the study
- Treatment with systemic immunostimulatory agents within 4 weeks or five half-lives of the drug (whichever is shorter) prior to randomization
- Treatment with systemic corticosteroids or other systemic immunosuppressive medications within 2 weeks prior to randomization, or anticipated requirement for systemic immunosuppressive medications during the trial
- Participants who are breastfeeding, or intending to become pregnant during the study