ForPatients
by Roche

Triple Negative Breast Cancer

A Study of Atezolizumab and Paclitaxel Versus Placebo and Paclitaxel in Participants With Previously Untreated Locally Advanced or Metastatic Triple Negative Breast Cancer (TNBC)

Trial Status	Trial Runs In	Trial Identifier
Completed	24 Countries	NCT03125902 2016-004024-29 MO39196

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 Phase III, Multicenter, Randomised, Double-Blind, Placebo-Controlled Study of Atezolizumab (Anti-Pd-L1 Antibody) in Combination With Paclitaxel Compared With Placebo With Paclitaxel for Patients With Previously Untreated Inoperable Locally Advanced or Metastatic Triple Negative Breast Cancer

Trial Summary:

This Phase 3, multicenter, randomized, double-blind, placebo controlled study is designed to evaluate the efficacy and safety of atezolizumab (MPDL3280A, an anti-programmed death-ligand 1 [PD-L1] antibody) administered in combination with paclitaxel compared with placebo in combination with paclitaxel in participants with previously untreated, inoperable locally advanced or metastatic, centrally confirmed TNBC. Participants will be randomized in a 2:1 ratio to receive atezolizumab or placebo plus paclitaxel until disease progression or unacceptable toxicity or end of study, whichever occurs first (maximum up to approximately 40 months). In addition, the Sponsor may decide to terminate the study at any time.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03125902 2016-004024-29 MO39196
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Participants with locally advanced or metastatic, histologically documented TNBC (absence of human epidermal growth factor receptor 2 [HER2], estrogen receptor [ER], and progesterone receptor [PR] expression), not amenable to surgical therapy
- Participants eligible for taxane monotherapy
- No prior chemotherapy or targeted systemic therapy (including endocrine therapy) for inoperable locally advanced or metastatic TNBC
- Availability of formalin-fixed paraffin-embedded (FFPE) tumor block (preferred) or at least 17 unstained slides, collected #3 months prior to randomization, with an associated pathology report, if available. If a tumour sample taken within 3 months before randomisation is not available and a tumour biopsy is not clinically feasible, the primary surgical resection sample or the most recent FFPE tumour biopsy sample may be used. Of these additional options, the most recent sample should be used.
- Eastern Cooperative Oncology Group performance status of 0 or 1
- Life expectancy at least 12 weeks
- Measurable disease, as defined by RECIST v1.1
- Adequate hematologic and end-organ function
- Negative human immunodeficiency virus (HIV) test at screening.
- Negative hepatitis B surface antigen (HBsAg) test at screening
- Negative total hepatitis B core antibody (HBcAb) test at screening, or positive HBcAb test followed by a negative hepatitis B virus (HBV) DNA test at screening. The HBV DNA test will be performed only for patients who have a positive HBcAb test.
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening. The HCV RNA test will be performed only for patients who have a positive HCV antibody test.
- Women of child bearing potential must have a negative serum pregnancy test result within 7 days prior to initiation of study drug
- For men and women of child bearing potential: agreement to remain abstinent or use protocol defined contraceptive measures during the treatment period and for at least 5 months after the last dose of atezolizumab/placebo, or for at least 6 months after the last dose of paclitaxel

Exclusion Criteria:

- 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 at least 2 weeks prior to randomization
- Known central nervous system (CNS) disease, except for treated asymptomatic CNS metastases
- Leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites
- Uncontrolled tumor-related pain, or uncontrolled hypercalcemia or clinically significant (symptomatic) hypercalcemia
- Malignancies other than TNBC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome (such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer)
- Pregnant or breast-feeding women, or intending to become pregnant during the study
- Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results, including significant liver disease, cardiovascular disease, and presence of an abnormal electrocardiogram (ECG)
- Serious infection requiring antibiotics within 2 weeks prior to randomization, including but not limited to infections requiring hospitalization or IV antibiotics, such as bacteremia, or severe pneumonia

- Major surgical procedure within 4 weeks prior to randomization or anticipation of the need for a major surgical procedure during the study other than for diagnosis
- Treatment with investigational therapy within 30 days prior to initiation of study treatment
- History of hypersensitivity reactions to study drug or any component of the study drug formulation