ForPatients
by Roche

Triple Negative Breast Cancer

A Study to Investigate Atezolizumab and Chemotherapy Compared With Placebo and Chemotherapy in the Neoadjuvant Setting in Participants With Early Stage Triple Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT03197935 2016-004734-22 WO39392

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 Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Neoadjuvant Anthracycline/Nab-Paclitaxel-Based Chemotherapy Compared With Placebo and Chemotherapy in Patients With Primary Invasive Triple-Negative Breast Cancer

Trial Summary:

This is a global Phase III, double-blind, randomized, placebo-controlled study designed to evaluate the efficacy and safety of neoadjuvant treatment with atezolizumab (anti-programmed death-ligand 1 [anti-PD-L1] antibody) and nab-paclitaxel followed by doxorubicin and cyclophosphamide (nab-pac-AC), or placebo and nab-pac-AC in participants eligible for surgery with initial clinically assessed triple-negative breast cancer (TNBC).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Histologically documented TNBC (negative human epidermal growth factor receptor 2 [HER2], estrogen receptor [ER], and progesterone receptor [PgR] status)
- Confirmed tumor programmed death-ligand 1 (PD-L1) evaluation as documented through central testing of a representative tumor tissue specimen
- Primary breast tumor size of greater than (>) 2 centimeters (cm) by at least one radiographic or clinical measurement
- Stage at presentation: cT2-cT4, cN0-cN3, cM0
- Participant agreement to undergo appropriate surgical management including axillary lymph node surgery and partial or total mastectomy after completion of neoadjuvant treatment
- Baseline left ventricular ejection fraction (LVEF) greater than or equal to (>=) 53 percent (%) measured by echocardiogram (ECHO) or multiple-gated acquisition (MUGA) scans
- Adequate hematologic and end-organ function
- Representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in paraffin blocks (preferred) or at least 20 unstained slides, with an associated pathology report documenting ER, PgR, and HER2 negativity
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm
- Women who are not postmenopausal or have undergone a sterilization procedure must have a negative serum pregnancy test result within 14 days prior to initiation of study drug

Exclusion Criteria:

- Prior history of invasive breast cancer
- Stage 4 (metastatic) breast cancer
- Prior systemic therapy for treatment and prevention of breast cancer
- Previous therapy with anthracyclines or taxanes for any malignancy
- History of ductal carcinoma in situ (DCIS), except for participants treated exclusively with mastectomy >5 years prior to diagnosis of current breast cancer
- History of pleomorphic lobular carcinoma in situ (LCIS), except for participants surgically managed >5 years prior to diagnosis of current breast cancer
- Bilateral breast cancer
- Undergone incisional and/or excisional biopsy of primary tumor and/or axillary lymph nodes
- Axillary lymph node dissection prior to initiation of neoadjuvant therapy
- History of other malignancy within 5 years prior to screening, with the exception of those with a negligible risk of metastasis or death
- Cardiopulmonary dysfunction
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells
- Known allergy or hypersensitivity to the components of the formulations of atezolizumab, nab-paclitaxel, cyclophosphamide, or doxorubicin, filgrastim or pegfilgrastim
- Active or history of autoimmune disease or immune deficiency diseases except history of autoimmune-related hypothyroidism, controlled Type 1 diabetes mellitus, and dermatologic manifestations of eczema, psoriasis, lichen simplex chronicus, or vitiligo (e.g., participants with psoriatic arthritis are excluded)
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Positive human immunodeficiency virus (HIV) test at screening

- Active hepatitis B and hepatitis C virus infection
- Active tuberculosis
- Severe infections within 4 weeks prior to initiation of study treatment, including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment, except prophylactic antibiotics
- Major surgical procedure within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during the course of the study
- Prior allogeneic stem cell or solid organ transplantation
- Administration of a live attenuated vaccine within 4 weeks prior to initiation of study treatment or anticipation of need for such a vaccine during the study
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the participant at high risk from treatment complications
- Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint-blockade therapies, including anti-cluster of differentiation 40 (anti-CD40), anti-cytotoxic T-lymphocyte-associated protein 4 (anti-CTLA-4), anti-programmed death-1 (anti-PD-1), and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 half-lives of the drug, whichever is longer, prior to initiation of study treatment
- Treatment with systemic immunosuppressive medications within 2 weeks prior to initiation of study treatment or anticipation of need for systemic immunosuppressive medications during the study
- History of cerebrovascular accident within 12 months prior to randomization
- Pregnant or lactating, or intending to become pregnant during the study