

Câncer da Mama Triplo-Negativo

**Um estudo para investigar atezolizumabe e quimioterapia em comparação com placebo e quimioterapia no cenário neoadjuvante em participantes com câncer de mama triplo negativo em estágio inicial**

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**  
Concluído

**Trial Runs In**  
13 Countries

**Trial Identifier**  
NCT03197935 2016-004734-22  
WO39392

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

**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

**NCT03197935 2016-004734-22 WO39392**  
Trial Identifiers

**Eligibility Criteria:**

**Gender**  
All

**Age**  
# 18 Years

**Healthy Volunteers**  
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 ( $\geq$ ) 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)

# ForPatients

*by Roche*

- 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