Protocol Title: A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo

Target Population: Triple Negative Breast Cancer (TNBC)

Summary: The main purpose of this study is to learn if usual neoadjuvant chemotherapy for breast cancer plus the experimental drug, Atezolizumab, is better than usual chemotherapy plus placebo. Usual chemotherapy in this study is Paclitaxel and Carboplatin followed by Doxorubicin & Cyclophosphamide or Epirubicin & Cyclophosphamide. Usually, after neoadjuvant therapy and surgery for TNBC, no additional treatment is given unless cancer returns. This study will also look at continuing treatment after surgery with Atezolizumab or placebo.

Key Inclusion Criteria:
- Diagnosis of invasive adenocarcinoma of the breast must have been made by core needle biopsy that is determined to be ER-negative, PR-negative, and HER2-negative by current ASCO/CAP guidelines.
- ECOG Performance Status must be 0-1.
- Primary tumor can be clinical stage T2 or T3, if clinically node negative according to AJCC 7th Edition.
  - If regional lymph nodes are cN1 and cytologically or histologically positive or cN2-N3 with or without a biopsy, the primary breast tumor can be clinically T1c, T2, or T3.
- Ipsilateral axillary lymph nodes must be evaluated by imaging within 84 days prior to study entry.
- Patients with synchronous bilateral or multicentric HER2-negative breast cancer are eligible as long as the highest risk tumor is ER-negative and PR-negative and meets stage eligibility criteria and also HER2-negative.
- Patients with N2 or N3 nodal disease or T3 primary disease must undergo liver and bone imaging within 28 Days prior to randomization, irrespective of baseline labs, and studies must not demonstrate metastatic disease.
- Adequate bone marrow and organ function.

Key Exclusion Criteria:
- Excisional biopsy or lumpectomy performed prior to study entry.
- FNA alone to diagnose the breast cancer.
- Surgical axillary staging procedure prior to randomization.
  - Exception: FNA or core biopsy of an axillary node is permitted for any patient. A pre-neoadjuvant therapy sentinel lymph node biopsy for patients with clinically negative axillary nodes is prohibited.
- Definitive clinical or radiologic evidence of metastatic disease.
- Previous history of contralateral invasive breast cancer.
- Previous history of ipsilateral invasive breast cancer or ipsilateral DCIS.
- History of non-breast malignancies (except for in situ cancers treated only by local excision and basal cell and squamous cell carcinomas of the skin) within 5 Years prior to study entry.
- Treatment including radiation therapy, chemotherapy, or targeted therapy, for the currently diagnosed breast cancer prior to randomization.
- Previous therapy with Anthracyclines or Taxanes for any malignancy.
- Prior allogeneic stem cell or solid organ transplantation.
- Prior treatment with CD137 agonists or immune checkpoint-blockade therapies, including anti-CD40, anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03281954