**Protocol Title:** Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy

**Target Population:**
- Estrogen Receptor, HER2/Neu, Progesterone Receptor Negative
- Triple-Negative Breast Carcinoma
- Stage IIA - IIIC Breast Cancer

**Summary:** To compare the Invasive Disease-Free Survival (IDFS) in Triple-Negative Breast Cancer (TNBC) patients with residual basal-like disease after neoadjuvant chemotherapy who are randomized to post-preoperative platinum based chemotherapy with those who are randomized to Capecitabine.

**Key Inclusion Criteria:**
- Female and Male patients must have histologically confirmed Triple Negative Non-Metastatic Breast Cancer.
- ER- and PR- should meet 1 of the following criteria:
  - ≤ 10% cells stain positive, with weak intensity score (Allred score ≤ 3).
  - ≤ 1% cells stain positive, with weak or intermediate intensity score (Allred score ≤ 3).
- Patients must have completed neoadjuvant Taxane +/- Anthracycline.
- Must have completed definitive resection of primary tumor.
  - Patients with positive margins for DCIS may enroll if the treatment team believes no further surgery is possible and patient has received radiotherapy; patients with margins positive for lobular carcinoma in situ (LCIS) are eligible.
  - Axillary dissection is encouraged in patients with lymph node involvement, but is not mandatory.
- Post neoadjuvant chemotherapy, patients must be found to have residual invasive cancer at the time of definitive surgery measuring ≥ 1 cm in diameter, and with more than minimal cellularity, as per local pathologist determination.
- Post-mastectomy radiotherapy is required for all patients with the following: primary tumor ≥ 5 cm or involvement of 4 or more lymph nodes at the time of definitive surgery.

**ELIGIBILITY CRITERIA FOR RANDOMIZATION (STEP 1):**
- For patients randomized to the chemotherapy arms, cycle 1/day 1 (platinum based or Capecitabine) must start within 1 Week (5 working Days) following randomization.
- Must have PAM50 analysis on the formalin-fixed paraffin-embedded tumor tissue specimen (FFPE) of the residual disease in the breast or axilla post-chemotherapy.
- ECOG performance status 0 or 1.

**Key Exclusion Criteria:**
- Patients must NOT have received Cisplatin, Carboplatin, or Capecitabine as part of their neoadjuvant therapy regimen.
- Patients with active ≥ Common Terminology Criteria for Adverse Events (CTCAE) Grade 2 Neuropathy are ineligible.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT02445391](https://clinicaltrials.gov/ct2/show/NCT02445391)