For Patients with Breast Cancer

EA1131 Available Through ECOG-ACRIN Cancer Research Group
A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Breast Cancer following Neoadjuvant Chemotherapy

**Patient Population**
See Section 3.0 for Complete Eligibility Details

**Screening and Molecular Profiling Eligibility (Step 0):**
- Age ≥18 years, ECOG PS 0-1, and adequate lab values
- Must have histologically confirmed invasive breast cancer that meets the criteria per protocol
- Must have completed neoadjuvant taxane +/- anthracycline; must not have received cisplatin, carboplatin, or capecitabine as part of their neoadjuvant regimen (see protocol for exceptions)
- Must have completed definitive resection of primary tumor (see protocol for additional details)
- Post neoadjuvant chemotherapy, patients must be found to have residual invasive cancer in the breast at the time of definitive surgery (measuring ≥ 1 cm in the biggest lesion, with more than minimal cellularity); DCIS without invasion does not qualify
- Post-mastectomy radiotherapy is required for certain patients per protocol; breast radiotherapy (whole or partial) is required for patients who underwent breast-conserving therapy, including lumpectomy or partial mastectomy
- No history of TNBC invasive breast cancer within 5 years of enrollment; no concurrent malignancies
- No patients with active ≥ CTCAE v4 gr 2 neuropathy
- No adjuvant chemotherapy after surgery other than that specified per protocol

**Randomization Eligibility (Step 1):**
- Must have PAM50 analysis by digital mRNA quantitation on the FFPE of the residual disease in the breast resected at the time of definitive surgery completed
- Radiotherapy may be given before or after protocol treatment, but if given prior, must be completed ≥ 2 weeks before randomization, if applicable
- Randomization within 24 weeks from surgery
- Not pregnant or breast-feeding
- Adequate lab values

**Treatment Plan**
See Section 5.0 for Complete Treatment Details

**Arm A:** Observation; closed to accrual in Add. #3

**Arm B:**
- Cisplatin 75 mg/m², IV infusion per institutional guidelines, day 1 every 3 weeks OR
- Carboplatin AUC 6, IV infusion per institutional guidelines, day 1 every 3 weeks
- Repeat cycles every 3 weeks for a total of 4 cycles (12 weeks)

**Notes:**
- Doses are based on actual body weight
- The Calvert Formula is used for carboplatin dosing
- Choice of platinum agent will be per treating physician; once a platinum agent is picked, no changes are allowed
- Treatment cycles should be no less than 19 days apart
- All patients will be followed for development of recurrences, second primary cancer and survival based on standard ECOG-ACRIN following schedules

**Arm C:**
- Capecitabine 1000 mg/m², PO twice daily, on days 1-14 every 3 weeks for a total of 6 cycles (18 weeks)

**Notes:**
- Treatment cycles should be no less than 19 days apart
- See protocol for guidance on rounding capecitabine; adjustments based on weight changes are not necessary until there is ≥ 10% change in weight compared to baseline
- Tablets should be swallowed whole, 30 minutes after a meal
- Dose escalations after dose reductions for safety are not permitted
- Missed doses beyond 3 hours of regular intake time should not be taken; dose should not be replaced if vomited

**Study Chair:**
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**Co-Chair:**
Carlos L. Arteaga, M.D.

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

**Protocol Information**

Please Enroll Your Eligible Patients!