**Protocol Title:** Phase II Randomized Placebo-Controlled Trial of Cisplatin With or Without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer

**Target Population:** Stage IV Triple-Negative Breast Cancer and/or BRCA Mutation-associated Breast Cancer.

**Summary:** To compare the efficacy of Cisplatin with or without ABT-888 (Veliparib) on Progression-Free Survival (PFS) in each of the following groups: patients with germline BRCA (gBRCA) Mutation-associated Breast Cancer, patients with Germline BRCA Wild-Type Breast Cancer who have evidence of BRCAness phenotype, and patients with Germline BRCA Wild-Type Breast Cancer who do not have evidence of BRCAness phenotype.

- **Brain Metastases Cohort:** To compare the efficacy of cisplatin with or without ABT-888 on PFS in patients with triple negative and/or gBRCA mutation-associated breast cancer and brain metastases.

**Key Inclusion Criteria:**

- Patients must have Metastatic Breast Cancer (Stage IV) and be Human Epidermal Growth Factor Receptor 2 (HER2) non-over expressing.
- Patients must also meet at least one of the following criteria Triple Negative or BRCA Mutation.
- Patients must have measurable or non-measurable disease, confirmed by Chest / Abdominal CT Scan or PET/CT of diagnostic quality, conventional, or spiral and Bone Scan prior to registration.
- Patients must have had ≤1 prior cytotoxic regimen for metastatic disease.
- Patients must have completed any prior radiation therapy and hormonal therapy ≥14 Days prior to registration.
- Patients must not have received prior Cisplatin or PolyADP-Ribose Polymerase (PARP) Inhibitors.
  - Prior Carboplatin in the adjuvant/neoadjuvant setting and prior treatment with Iniparib is allowed, if completed >6 Months prior to study entry.
- Patients must not have received any immunotherapy, biologic, or any investigational drug within 28 Days prior to registration.
  - Patients must not have received Bevacizumab within 42 Days prior to registration.
- Patients may receive Bisphosphonates or Denosumab concurrently with study treatment provided it has been started at least 7 Days prior to registration.
- Patients must not have a clinically relevant hearing impairment ≥grade 2.
- Patients must not have baseline peripheral neuropathy that exceeds grade 1.
- **BRAIN METASTASES COHORT:**
  - In addition to all of the previous eligibility criteria, patients with progressive brain metastases who do not satisfy the conditions to enroll in the standard cohort must also meet the following criteria:
    - Patients with progressive Brain Metastases must have a baseline Brain MRI within 28 Days prior to registration.
      - Brain Metastases must be progressive and ≥10 mm in longest dimension on radiographic imaging AFTER prior intracranial radiation (IR), patients must not have evidence of diffuse Leptomeningeal Disease on Brain MRI or by previously documented CSF cytology.
      - Discrete Dural Metastases are permitted.
      - There must be no evidence of hemorrhage or impending herniation on baseline brain imaging.
    - Patients must be on a stable or decreasing dose of steroids for ≥7 Days prior to registration.
    - If patient had an open brain biopsy, at least 28 Days must have elapsed between biopsy and registration.

**Contacts:**

- **Principal Investigator:** John T. Cole, MD
- **Research Nurses (RN):** Socea May (smay@ochsner.org, ext. 22373)
  Jessica Rentfrow (jessica.rentfrow@ochsner.org, ext. 32652)

For additional information: [https://clinicaltrials.gov/ct2/show/NCT02595905](https://clinicaltrials.gov/ct2/show/NCT02595905)

IRB# 2017.061 N