**Protocol Title:** Phase 1b Clinical Study of CBP501, Cisplatin and Nivolumab Administered Every 3 Weeks in Patients with Advanced Refractory Tumors

**Target Population:** Adults with Advanced Solid Tumors

**Summary:** This is a multicenter, open-label, phase 1b study of CBP501/Cisplatin/Nivolumab combination administered once every 21 Days to patients with Advanced Solid Tumors.

**Key Inclusion Criteria:**
- Previously treated, pathologically confirmed, locally advanced or metastatic solid tumors with measureable disease.
- Males or female patients aged ≥ 18 Years at the time of informed consent.
- ECOG Performance Status of 0-1.
- Previously anticancer treatment must be discontinued at least 3 Weeks prior to the initiation of study treatment.
  - 6 Weeks for Mitomycin C
  - 6 Weeks for Anti-androgen therapy if discontinued prior to treatment initiation, except 8 Weeks for Bicalutamide
- Adequate bone marrow reserve, cardiac, liver, renal, and metabolic function.
- Female patients of child-bearing potential must have a negative pregnancy test and use at least one form of contraception as approved by the investigator for 4 Weeks prior to initiating study treatment and 4 Months after the last dose of study drug.
- Male patients must use a form of barrier contraception approved by the investigator during the study and for 4 Months after the last dose of study drug.

**Key Exclusion Criteria:**
- Radiation therapy to > 30% of bone marrow prior to study entry.
- Prior chemotherapy with Nitrosoureas, prior Mitomycin C cumulative dose ≥ 25 mg/m², prior bone marrow transplant, or prior intensive chemotherapy with stem cell support.
- Presence of any serious concomitant systemic disorders incompatible with the study in the option of the investigator.
- Any previous history of another malignancy within 5 Years of study entry, except for:
  - Cured Basal Cell or Squamous Cell Carcinoma of the Skin
  - Cured in situ carcinoma
- Presence of any significant CNS or psychiatric disorders that would hamper the patient’s compliance.
- Evidence of peripheral neuropathy > grade 1 by NCI-CTCAE version 4.03.
- Treatment with other investigational agent or participation in another clinical trial within 28 Days prior to study.
- Pregnant or breast-feeding patients or any patients with child-bearing potential not using contraception.
- Known HIV, HBV, or HCV infection.
- Active CNS metastases.
  - However, patients with CNS metastases will be eligible if they have been treated and are stable without symptoms for 4 Weeks after completion of treatment, with image documentation required, and must be off steroids.

**Contacts:**
- **Principal Investigator:** Marc Matrana, MD
- **Research Nurses (RN):** Amanda Woolery (amandawoolery@ochsner.org, ext. 20275)
  Sharon Jerdonek (sharonjerdonek@ochsner.org, ext. 23929)

**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT03113188](https://clinicaltrials.gov/ct2/show/NCT03113188)