Protocol Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase III Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy (ATHENA)

Target Population: Newly diagnosed FIGO Stage III – IV Epithelial Ovarian Cancer, Primary Peritoneal Cancer, or Fallopian Tube Cancer

Summary: This is a Phase III, randomized, multinational, double-blind, dual placebo-controlled, 4-arm study evaluating Rucaparib and Nivolumab as maintenance treatment following response to front-line treatment in newly diagnosed Ovarian Cancer patients. Response to treatment will be analyzed based on homologous recombination (HR) status of tumor samples.

Key Inclusion Criteria:
- Newly diagnosed advanced (FIGO stage III-IV) Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.
- Completed cytoreductive surgery, including at least a bilateral salpingo-oophorectomy and partial omentectomy, either prior to chemotherapy (primary surgery) or following neoadjuvant chemotherapy (interval debulking).
- Completed first-line platinum-based chemotherapy and surgery with a response, in the opinion of the Investigator.
- Sufficient tumor tissue for planned analysis.
- ECOG Performance Status of 0 or 1.

Key Exclusion Criteria:
- Pure Sarcomas or borderline tumors or mucinous tumors.
- Active second malignancy.
- Known Central Nervous System brain metastases.
- Any prior treatment for Ovarian Cancer, other than the first-line platinum regimen.
- Evidence of interstitial lung disease or active pneumonitis.
- Active, known or suspected autoimmune disease.
- Condition requiring active systemic treatment with either corticosteroids (>10 mg daily prednisone equivalent) or other immunosuppressive medications.

Contacts:
- Principal Investigator: Katrina Wade, MD
- Research Nurses (RN): Amanda Struckhoff (amanda.struckhoff@ochsner.org, ext. 23682)
  April Wendt (awendt@ochsner.org, ext. 24548)

For additional information: https://clinicaltrials.gov/ct2/show/NCT03522246