Protocol Title: A Phase I/II Study of Ruxolitinib with Front-Line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Target Population: Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer

Summary: This phase I/II partially randomized trial studies the side effects and the best dose of Ruxolitinib Phosphate when given together with Paclitaxel and Carboplatin and to see how well they work in treating patients with Stage III-IV Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Key Inclusion Criteria:
- Must have clinically and radiographically suspected and previously untreated FIGO Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer, high grade, for whom management plan will include neoadjuvant chemotherapy with interval tumor reductive surgery who have undergone biopsies for histologic confirmation
- Institutional confirmation of Müllerian epithelial adenocarcinoma on core biopsy or laparoscopic biopsy
- The following histologic epithelial cell types are eligible: high grade serous carcinoma, high grade endometrioid carcinoma, clear cell carcinoma, or a combination of these
- Must have measurable disease as defined by RECIST 1.1
- ECOG/Karnofsky Performance Status of 0, 1, or 2 within 28 Days prior to registration
- Adequate hematologic, renal, and hepatic function within 14 Days prior to registration
- Neurologic function: Neuropathy (sensory and motor) less than or equal to CTCAE Grade 1

Key Exclusion Criteria:
- Suspected non-gynecologic malignancy, such as gastrointestinal
- History of other invasive malignancies, with exception of non-melanoma skin cancer and other specific malignancies, are excluded if there is any evidence of malignancy being present in the last 3 Years (2 Years for breast cancer)
- Received prior chemotherapy for any abdominal or pelvic tumor within the last 3 Years
- Received prior radiotherapy to any portion of abdominal cavity or pelvis or thoracic cavity within last 3 Years
- Received any targeted therapy (including but not limited to vaccines, antibodies, tyrosine kinase inhibitors) or hormonal therapy for management of their epithelial ovarian, fallopian tube or peritoneal primary cancer
- Mucinous carcinoma, low grade endometrioid carcinoma, low grade serous carcinoma or carcinosarcoma
- Synchronous primary endometrial cancer, or a past history of primary endometrial cancer, unless all of the following conditions are met: Stage not greater than I-A, grade 1 or 2, no more than superficial myometrial invasion, without vascular or lymphatic invasion; no poorly differentiated subtypes, including serous, clear cell or other FIGO grade 3 lesions
- Severe, active co-morbidity
- Not candidates for major abdominal surgery due to known medical comorbidities
- Any condition that in the judgment of the PI would jeopardize safety or patient compliance with the protocol
- Unwilling to be transfused with blood components
- Concurrent anticancer therapy (e.g. chemotherapy, radiation therapy, biologic therapy, immunotherapy, hormonal therapy, investigational therapy)
- Patients who, in the opinion of the PI, are unable or unlikely to comply with dosing schedule and evaluations

Contacts:
Principal Investigator: Katrina Wade, MD
Research Nurses (RN): Amanda Struckhoff (amanda.struckhoff@ochsner.org, ext. 23682)
Amanda Woolery (amanda.woolery@ochsner.org, ext. 20275)

For additional information: https://clinicaltrials.gov/ct2/show/NCT02713386