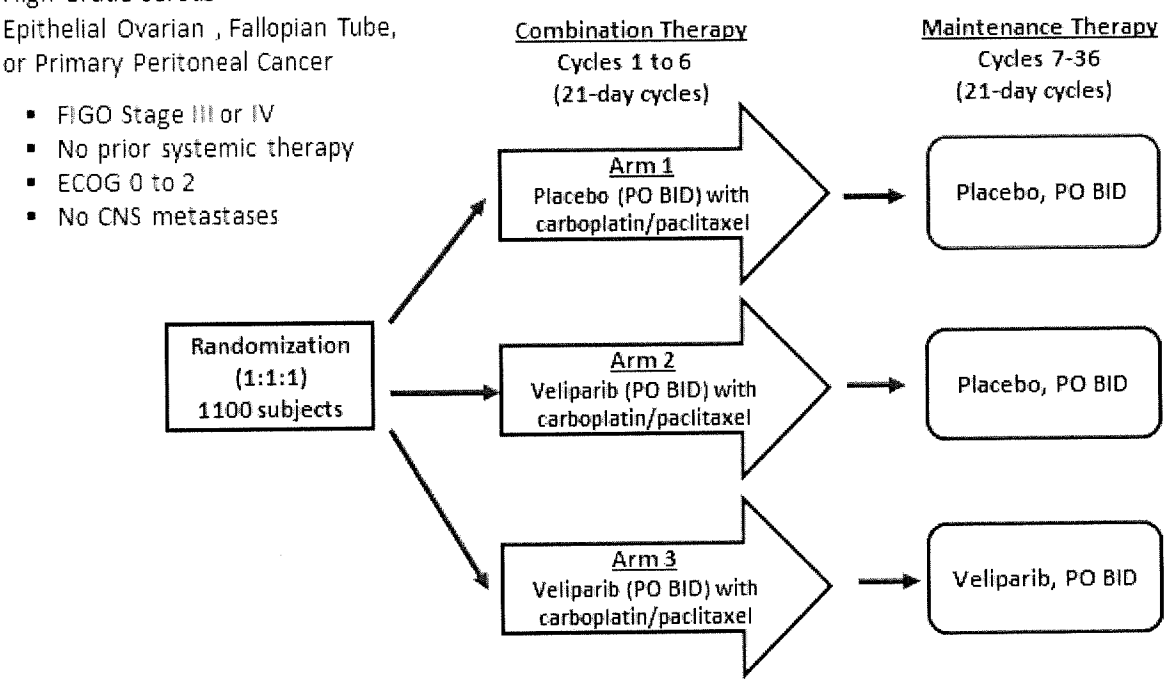
Study Summary

Protocol Title: GOG 3005 (AbbVie M13-694): A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Study Purpose: The primary objective of the study is to evaluate whether PFS is prolonged with the addition of veliparib to standard platinum-based chemotherapy (carboplatin/paclitaxel) and then continued as maintenance therapy when compared to chemotherapy alone. This will be evaluated in the whole patient population, as well as a more selective cohort of subjects with BRCA-deficient tumors.

Study Design:



Endpoints: Endpoints will be evaluated both in the whole subject population and in subjects with BRCA-deficient tumors as follows:

- **Primary Objective:** PFS (Arm 3 versus Arm 1)
- **Secondary Objectives:**
  - PFS (Arm 2 versus Arm 1)
  - OS (Arm 3 versus Arm 1)
  - OS (Arm 2 versus Arm 1)
  - DRS Scores (All Arms)

Choice of Therapy: All subjects will receive:

- Carboplatin AUC 6 Q3-weeks plus
- Paclitaxel Q-week (80 mg/m^2), OR Palitaxel Q3-weeks (175 mg/m^2)
- Surgery
  - Primary cytoreductive, OR
  - Interval cytoreductive

BID = twice daily; CNS = central nervous system; ECOG = Eastern Cooperative Oncology Group; FIGO = International Federation of Gynecology and Obstetrics; OS = overall survival; PFS = progression-free survival; PO = oral; PRO = patient-reported outcomes, Q-week = weekly; Q3-weeks = every 3 weeks

Subject Eligibility: **Inclusion Criteria:**

-Subjects with a histologic diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, FIGO Stage III or IV with appropriate tissue available for histologic evaluation.
-Subjects will be required to have high-grade serous adenocarcinoma to be eligible.
-Subject is willing to undergo testing for gBRCA.
-Subjects with neuropathy (sensory and motor) less than or equal to Grade 1.
-Subjects must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.
-Subjects who undergo primary cytoreductive surgery must be entered between 1 and 12 weeks after surgery.
-Subjects undergoing interval cytoreductive surgery must have a needle core biopsy confirming the histological diagnosis prior to enrollment.
-Subjects with measurable disease and non-measurable disease are eligible. Subjects may or may not have cancer-related symptoms.

Exclusion Criteria:

-Subjects with the following histologic cell types are ineligible: endometrioid adenocarcinoma, carcinosarcoma, undifferentiated carcinoma, mixed epithelial adenocarcinoma, adenocarcinoma not otherwise specified, mucinous adenocarcinoma, clear cell adenocarcinoma, low-grade serous adenocarcinoma,
transitional cell carcinoma, or malignant Brenner's tumor.
-Subjects with synchronous primary endometrial cancer, or a past history of endometrial cancer unless all of the following conditions are met: endometrial
cancer stage not greater than IA, no vascular or lymphatic invasion, no poorly differentiated subtypes including serous, clear cell, or other FIGO grade 3 lesions.
-Subjects with a history of other invasive malignancies, with the exception ofnon-melanoma skin cancer, are excluded if there is any evidence of other malignancy being present within the last 3 years. Subjects are also excluded if their previous cancer treatment contraindicates this protocol's therapy.
-Subjects who have received prior radiotherapy to any portion of the abdominal cavity or pelvis are excluded.
-Subjects who have received prior chemotherapy for any abdominal or pelvic tumor are excluded.

Principal Investigator: Abbie Fields, MD

For more information about this study and to inquire about eligibility, please contact the Research Staff at 410-601-6120.

Locations

Sinai Hospital of Baltimore, Inc.

ClinicalTrials.gov
Visit **ClinicalTrials.gov** for full clinical trial description