"A PHASE III RANDOMIZED CONTROLLED CLINICAL TRIAL OF CARBOPLATIN AND PACLITAXEL (OR GEMCITABINE) ALONE OR IN COMBINATION WITH BEVACIZUMAB (NSC #704865, IND #113912) FOLLOWED BY BEVACIZUMAB AND SECONDARY CYTOREDUCTIVE SURGERY IN PLATINUM-SENSITIVE, RECURRENT OVARIAN, PERITONEAL PRIMARY AND FALLOPIAN TUBE CANCER. NCI-SUPPLIED AGENTS: BEVACIZUMAB"

Protocol

GOG 0213

Purpose:

- To determine if surgical secondary cytoreduction in addition to adjuvant chemotherapy increases the duration of overall survival in patients with recurrent platinum sensitive epithelial ovarian cancer, peritoneal primary or Fallopian tube cancer.

- To determine if the addition of bevacizumab to the second-line and maintenance phases of treatment increases the duration of overall survival relative to second-line paclitaxel and carboplatin alone in patients with recurrent platinum sensitive epithelial ovarian cancer, peritoneal primary or Fallopian tube cancer.

Investigator

Fouad Abbas, M.D.

Eligibility

To be eligible for this study, patients must meet several criteria, **including but not limited** to the following:

- Patients enrolled after August 28, 2011 must be candidates for cytoreductive surgery and consent to have their surgical treatment determined by randomization
- Patients must have histologic diagnosis of epithelial ovarian carcinoma, peritoneal primary or Fallopian tube carcinoma, which is now recurrent.
- Patients with the following histologic epithelial cell types are eligible: Serous adenocarcinoma, endometrioid adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, transitional cell carcinoma, malignant Brenner's Tumor, or adenocarcinoma not otherwise specified (N.O.S.).
- Patients must have had a complete response to front-line platinum-taxane therapy.(at least 3 cycles)
- A complete response to front-line chemotherapy must include: negative physical exam, negative pelvic exam and normalization of CA125, if elevated at baseline. Although not required, any radiographic assessment of disease status (e.g. CT, MRI, PET/CT, etc)

obtained following the completion of primary therapy should be considered negative for disease.

- All patients must have also had a treatment-free interval without clinical evidence of progressive disease of at least 6 months from completion of front-line chemotherapy (both platinum and taxane). Front-line therapy may have included a biologic agent (i.e. bevacizumab).
- Front-line treatment may include maintenance therapy following complete clinical or pathological response. However, maintenance cytotoxic chemotherapy must be discontinued for a minimum of 6 months prior to documentation of recurrent disease. Patients receiving maintenance biological therapy **or hormonal therapy** are ELIGIBLE provided their recurrence is documented more than 6 months from primary cytotoxic chemotherapy completion (includes maintenance chemotherapy) AND a minimum 4 weeks has elapsed since their last infusion of biological therapy

Ineligibility

- Patients who have received more than one previous regimen of chemotherapy (maintenance is not considered a second regimen).
- Patients receiving concurrent immunotherapy, or radiotherapy.
- Patients who have received prior radiotherapy to any portion of the abdominal cavity or pelvis are excluded.
- Patients whom have already undergone secondary cytoreduction for recurrent disease are excluded

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
Northwest Hospital Center

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