Study Summary

Protocol Title: **NRG-GY003:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer

Study Purpose: To estimate the proportion of patients who have objective tumor response (complete or partial) by modified RECIST 1.1 in patients with persistent or recurrent epithelial ovarian, fallopian tube, primary peritoneal cancers, treated with nivolumab or the combination of nivolumab and ipilimumab and to assess the difference in ORR between patients treated with nivolumab versus those treated with the combination of nivolumab

Study Design: Group 1: Will receive the drug nivolumab for a maximum of 92 weeks or until the subject experiences unacceptable side effects or their tumor grows.

Group 2: Will receive the drug nivolumab for a maximum of 96 weeks and ipilimumab for 12 weeks or until the subject experiences unacceptable side effects or their tumor grows.

In both groups, after the subject has finished receiving these study drugs, the study doctor will continue to watch the subject for side effects and follow their condition every three months for the first two years and then every six months for the next three years after completion of their treatment with nivolumab.

Subject Criteria: Eligibility Criteria:

- Patients must have recurrent or persistent epithelial ovarian, fallopian tube, or primary peritoneal cancer with documented disease progression (disease not amendable to curative therapy). Histologic confirmation of the original primary tumor is required via the pathology report. NOTE: Patients with mucinous histology are NOT eligible.
- All patients must have measurable disease as defined by RECIST 1.1. Measurable disease is defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded). Each lesion must be $\geq$ 10 mm when measured by CT, MRI or caliper measurement by clinical exam; or $\geq$ 20 mm when measured by chest x-ray. Lymph nodes must be $\geq$ 15 mm in short axis when measured by CT or MRI.
- Patients must have at least one "target" lesion" to be used to assess response on this protocol as defined by RECIST 1.1. Tumors within a previously irradiated field will be designated as "non-target" lesions unless progression is documented or a biopsy is obtained to confirm persistence at least 90 days following completion of radiation therapy.
- Performance Status of 0, 1 or 2 within 28 days prior to registration.

Prior Therapy:

- Patients are allowed to have received up to three prior cytotoxic regimens for treatment of their epithelial ovarian, fallopian tube, or primary peritoneal cancer. They must have had one prior platinum-based chemotherapeutic regimen for management of primary disease, possibly including intra-peritoneal therapy, consolidation, biologic/targeted (non-cytotoxic) agents or extended therapy (maintenance/consolidation) administered after surgical or non-surgical assessment

- Patients are allowed to have received, but are not required to have received, one or two cytotoxic regimens for management of recurrent or persistent disease. (For the purposes of this study PARP inhibitors given for recurrent or progressive disease will be considered cytotoxic.) If two cytotoxic regimens had been received for management of recurrent or persistent disease, one of these regimens would have had to contain either a platinum or a taxane agent.

Ineligibility Criteria:

- Patients who have had prior therapy with nivolumab or with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune check point pathways.
- History of severe hypersensitivity reaction to any monoclonal antibody.
- Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer and other specific malignancies are excluded if there is any evidence of other malignancy being present within the last three years (2 years for breast cancer). Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.
- Patients who have received prior chemotherapy for any abdominal or pelvic tumor OTHER THAN for the treatment of ovarian, fallopian tube, or primary peritoneal cancer within the last three years are excluded. Patients may have received prior adjuvant chemotherapy and radiotherapy for localized breast cancer, provided that it was completed more than 2 years prior to registration, the patient remains free of recurrent or metastatic disease and hormonal therapy has been discontinued. Patients who have received prior radiotherapy to any portion of the abdominal cavity or pelvis or thoracic cavity within the last three years are excluded. Prior radiation for localized cancer of the head and neck or skin is permitted, provided that it was completed more than three years prior to registration, and the patient remains free of recurrent or metastatic disease

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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.
Northwest Hospital Center

ClinicalTrials.gov
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