Cancer Research Consortium of West Michigan
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FAST FACTS

NRG GY019 - A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum

Eligibility Criteria

1. Patients must have newly diagnosed, Stage II-IV low-grade serous ovarian cancer (submission of pathology report(s) required). Ovarian cancer = ovarian, fallopian tube and primary peritoneal cancers.

   NOTE: Patients with a prior history of serous borderline tumors but a new diagnosis ofStage II-IV low-grade serous ovarian cancer are eligible.

   - p53 immunohistochemistry (IHC) is required and must show nonaberrant pattern (nonaberrant p53 expression is consistent with normal/wildtype TP53). A copy ofthe pathology report that includes the diagnosis of low grade serous ovarian cancer and nonaberrant p53 IHC result must be submitted in RAVE.

   NOTE: If aberrant p53 expression is found on p53 IHC, the patient is NOT eligible (e.g., aberrant p53 expression is consistent with mutant TP53 and supports a diagnosis of high grade serous ovarian cancer).
2. Appropriate stage for study entry based on the following diagnostic workup:
   • History/physical examination within 14 days prior to registration;
   • Radiographic tumor assessment (see Table 4.1) within 28 days prior to registration;
3. Age ≥ 18
4. Patients must have undergone an attempt at maximal upfront cytoreductive surgery, with either optimal (<=1cm diameter residual disease/nodule) or suboptimal residual disease (>1 cm diameter residual disease/nodule) status allowed.
5. Patients must have undergone a bilateral salpingo-oophorectomy
6. Patients must have an ECOG Performance Status of 0, 1 or 2 within 14 days prior to registration (Appendix I).
7. Patients must be within ≤8 weeks of primary cytoreductive surgery at time of randomization.
8. Patients must be able to take per oral (P.O.) medications.
9. Patients must have adequate organ and marrow function as defined below:
   NOTE: Institutional/laboratory upper limit of normal = ULN
   a. Bone marrow function within 14 days prior to registration defined as follows:
      i. Absolute neutrophil count (ANC) greater than or equal to 1,500/mcl
      ii. Platelets greater than or equal to 100,000 cells/mcl
   b. Adequate renal function within 14 days prior to registration defined as follows:
      i. Creatinine less than or equal to 1.5 x ULN
   c. Adequate hepatic function within 14 days prior to registration defined as follows:
      i. Bilirubin less than or equal to 1.5 x ULN
      ii. ALT and AST less than or equal to 3 x ULN
10. The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the U.S., authorization permitting release of personal health information.

11. Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.

Ineligibility Criteria

1. Patients may not have received neoadjuvant or adjuvant chemotherapy or radiotherapy for the treatment of this disease.
2. Patients may not have received previous hormonal therapy for the treatment of this disease.
3. Patients with known hypersensitivity to letrozole or hypersensitivity/intolerance to carboplatin/paclitaxel therapy.
4. Patients with severe cardiac disease:
    a. Myocardial infarction or unstable angina within 6 months prior to registration.
    b. New York Heart Association (NYHA) Class II or greater congestive heart failure (Appendix II).3
5. Patients with known central nervous system metastases
6. Patients with active (except for uncomplicated urinary tract infection) or uncontrolled systemic infection.
7. Patients with ≥grade 2 baseline neuropathy
8. Known HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial.

NRG-GY019
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