# "Phase II single arm trial with combination of Everolimus and Letrozole in treatment of platinum resistant relapse or refractory or persistent ovarian cancer/endometrial cancer"

**Protocol**

CRAD001CUS242T

**Purpose**

To estimate the clinical benefit rate (CRPR) and stable disease at 3 months for woman with relapse or refractory ovarian or endometrial cancer.

**Investigator**

Dr. Kenneth Miller

**Inclusion Criteria:**

- Age 18-90
- Post-menopausal or post-oophorectomy.
- Performance status Less than or equal to ECOG 2
- Patients must have relapse or refractory or persistent epithelial ovarian, fallopian tube, primary peritoneal carcinoma or endometrial cancer. Histologic documentation of the original primary tumor is required via pathology report.
- Patients must have received treatment with a platinum-based chemotherapeutic regimen for management of primary disease containing carboplatin, cisplatin. This initial treatment may have included intraperitoneal therapy, consolidation, noncytotoxic agents (biologic/targeted therapy) or extended therapy administered after surgical or non-surgical assessment.
- Patients must have one of the following:

  a. Patients must have platinum-resistant disease, defined as progression < 12 months after completeion of first-or-second-line platinum based chemotherapy. The date (platinum-free interval) should be calculated from the last administered dose of platinum therapy.

  b. Platinum sensitive patients must have progressed/relapsed after receiving a second line platinum therapy.

  c. Patients with platinum-refractory primary disease, defined as having disease progression while receiving first-line platinum-based chemotherapy.

- Patients are allowed to receive, but are not required to receive, one additional cytotoxic regimen for management of relapse or refractory or persistent disease.
- Patients are allowed to have received, but are not required to have received, biologic/targeted therapy (e.g., bevacizumab and/or PARP inhibitor) as part of their primary treatment regimen or for management of relapse or refractory or persistent disease.
- Expected duration of life >=2 months.

**Exclusion criteria:**

- Patients currently receiving anticancer therapies or who have received anticancer therapies within 4 weeks of the start of Everolimus (including chemotherapy, antibody based therapy, etc.); radiation therapy within 2 weeks.
- Patients receiving hormonal agents (i.e., oral estrogen, topical estrogen)
- Known intolerance or hypersensitivity to Everolimus or other rapamycin analogs (e.g. sirolimus, temsirolimus) or to Letrozole.
- Known impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of oral Everolimus;
- Patients who have any severe and/or uncontrolled medical conditions such as:
  a. unstable angina pectoris, symptomatic congestive heart failure, myocardial infarction $\leq$6 months prior to start of Everolimus, serious uncontrolled cardiac arrhythmia, or any other clinically significant cardiac disease
  b. Symptomatic congestive heart failure of New York heart Association Class III or IV
  c. active (acute or chronic) or uncontrolled severe infection, liver disease such as cirrhosis, decompensated liver disease, and active or chronic hepatitis (i.e. quantifiable HBV-DNA and/or positive HbsAg, quantifiable HCV-RNA),
  d. known severely impaired lung function (spirometry and DLCO 50% or less of normal and $O_2$ saturation 88% or less at rest on room air),
  e. active, bleeding diathesis;
- Chronic treatment with corticosteroids or other immunosuppressive agents. Topical or inhaled corticosteroids are allowed;
- Patients who have a history of another primary malignancy, with the exceptions of: non-melanoma skin cancer, and carcinoma in situ of the cervix, uteri, or breast from which the patient has been disease free for $\geq$3 years;
- Patients previously treated with everolimus.

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