**Protocol Title:** Randomized Phase II / III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or Platinum-Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)

**Target Population:** Women with Recurrent Platinum-Resistant or Platinum-Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**Summary:**
- Phase II: To assess the efficacy and identify (in) active arm(s) of the combination of Cediranib and Olaparib, Cediranib alone, Olaparib alone, and physician's choice standard of care chemotherapy, as measured by Progression-Free Survival (PFS) in the setting of Recurrent Platinum-Resistant or Platinum-Refractory Ovarian, Primary Peritoneal or Fallopian Tube Cancer.
- Phase III: To assess the efficacy of the combination of Cediranib and Olaparib, and active monotherapy experimental arm(s) from Phase II, as measured by Overall Survival (OS) and PFS, as compared to physician's choice standard of care chemotherapy in women with Recurrent Platinum-Resistant or Platinum-Refractory Ovarian, Primary Peritoneal, or Fallopian Tube Cancer.

**Key Inclusion Criteria:**
- Histologically or cytologically confirmed Ovarian, Peritoneal, or Fallopian Tube Cancer and must have a histological diagnosis of either Serous or Endometrioid Cancer.
- Patients should have Recurrent Platinum-Resistant or Platinum-Refractory Disease.
- Phase II: Measurable disease.
- Phase III: Evaluable disease (measurable or non-measurable disease that is defined as Solid and / or Cystic Abnormalities OR Ascites and / or Pleural Effusion pathologically demonstrated disease-related in the setting of a CA125 ≥ 2 x the upper limit of normal.
- No more than 3 prior treatment regimens (including primary therapy; no more than 1 prior non-platinum based therapy in the platinum-resistant/refractory setting).
  - Hormonal therapies used as single agents (i.e. Tamoxifen, Aromatase Inhibitors) will not count towards this line limit.
- Patients may not have had a prior anti-angiogenic agent in the recurrent setting.
  - Prior use of Bevacizumab in the upfront or upfront maintenance setting is allowed.
- Patients may not have previously received a PARP-Inhibitor.
- Adequately controlled blood pressure (SBP ≤ 140 mmHg or DBP ≤ 90 mmHg).

**Key Exclusion Criteria:**
- Patients who have had chemotherapy or radiotherapy within 4 Weeks of starting treatment or those who have not recovered from adverse events due to agents administered more than 4 Weeks earlier.
  - Note: 6 Weeks for Nitrosoureas or Mitomycin C.
  - Patients may not have had hormonal therapy within 2 Weeks prior to entering the study.
  - Patients receiving Raloxifene for bone health as per FDA indication may remain on Raloxifene.
- Prior treatment affecting the VEGF/VEGFR pathway or the Angiopoietin pathway in the recurrent setting.
- Prior use of PARP-Inhibitors.
- Patients with untreated Brain Metastases, Spinal Cord Compression, or evidence of symptomatic Brain Metastases or Leptomeningeal Disease should not be included on this study.

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For additional information: [https://clinicaltrials.gov/ct2/show/study/NCT02502266](https://clinicaltrials.gov/ct2/show/study/NCT02502266)