For Patients with Metastatic Castrate Resistant Prostate Cancer

9984 Available Through the CTSU
A Randomized Phase 2 Study of Cediranib in Combination with Olaparib versus Olaparib Alone in Men with Metastatic Castration Resistant Prostate Cancer

Patient Population - 84 Patients
See Protocol Section 3 for Full Eligibility Details

- Confirmed progressive, metastatic castration-resistant prostate adenocarcinoma
  - Radiographic proof of metastasis
  - Serum testosterone <50ng/dL
  - Progression documented by rising PSA, new lesions on bone scan, or RECIST
- ≥2 prior lines therapy for mCRPC
- ≤2 prior cytotoxic chemotherapies for mCRPC
- Measurable disease by RECIST v1.1.
- Tumor lesion accessible for biopsy, cannot be used for RECIST response
- Agree to mandatory research tumor biopsies
- Controlled BP <140/90 mmHg; patients to monitor BP daily

Treatment Plan
See Protocol Section 5 for Full Treatment Details

- Patients must continue or start LHRH or GnRH agonists 4 wks prior or have had orchiectomy
- Randomized 1:1
  - Group 1: Cediranib 30 mg PO qd + Olaparib 200 mg PO bid
  - Group 2: Olaparib 200 mg PO bid
- Olaparib-only patients can cross over to the combination upon radiographic progression
- Treatment until disease progression or excessive toxicity
- Notes:
  - Baseline and on-treatment biopsies
  - One cycle = 28 days

Schema

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information
CTSU Help Desk: 1-888-823-5923, CTSUcontract@westat.com, www.ctsu.org; NCT02893917

Please Enroll Your Eligible Patients!

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