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

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<th>Patient Population - 84 Patients</th>
<th>Treatment Plan</th>
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<td>See Protocol Section 3 for Full Eligibility Details</td>
<td>See Protocol Section 5 for Full Treatment Details</td>
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| • Confirmed progressive, metastatic castration-resistant prostate adenocarcinoma  
  o Radiographic proof of metastasis  
  o Serum testosterone <50ng/dL  
  o 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 | • 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:  
  o Baseline and on-treatment biopsies  
  o One cycle = 28 days |

### Schema

```
R
N=42
Olaparib 200 mg bid
|
|-----------------|
| Mandatory pre-tx biopsy |

Cediranib 30 mg qd + Olaparib 200 mg bid
|
|-----------------|
| Mandatory on-tx biopsy (wk 4) |

Cross-over at progression
```

Tumor reassessment every 8 weeks for first 24 weeks, then every 12 weeks, and at any other time when clinically indicated

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