## Genitourinary

### PROSTATE CANCER: Hormone-Sensitive, Non-Metastatic, Asymptomatic

<table>
<thead>
<tr>
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</table>
| Uchio     | L. Huynh  | UCI 17-86: Phase 1 Trial of Efficacy and Feasibility of Robot Assisted Salvage Pelvic Lymph Node Dissection (RS-PLND) or Robot Assisted Salvage Pelvic Mass Resection (RS-PMR) Post-Robot Assisted Radical Prostatectomy | Salvage Pelvic Lymph Node Dissection or Pelvic Mass Resection | • Clinically determined lymph node metastases/pelvic mass metastases.  
• Underwent radical prostatectomy for the treatment of prostate cancer. | Open to accrual |
| Ahlering  | L. Huynh  | H51 2018-4305: Phase 2.5 Multi-Institution Randomized Prospective Clinical Trial Evaluating the Impact of Cytoreductive Radical Prostatectomy Combined with Best Systemic Therapy on Oncologic and Quality of Life Outcomes in Men with Newly Diagnosed Prostate Cancer | Cytoreductive Prostatectomy                   | • Metastases of prostate cancer > 1cm.  
• Eligible to undergo radical prostatectomy.  
• Willing to be randomized. | Pending activation |
| Uchio     | S. Bereta, P. Duffy, K. Corey | UCI 18-13: A Randomized Phase III, Open-Label Trial of Sipuleucel-T Administered to Patients on Active Surveillance for Newly Diagnosed Prostate Cancer | Anti-PAP via APCs                              | • Treatment naïve.  
• NCCN low to intermediate risk prostate cancer. | Open to accrual |
| Uchio     | S. Bereta, P. Duffy, K. Corey | UCI 17-41: A Multi-Center, Randomized, Assessor-Blind, Controlled Trial Comparing the Occurrence of Major Adverse Cardiovascular Events (MACEs) in Patients with Prostate Cancer and Cardiovascular Disease Receiving Degarelix (GnRH Receptor Antagonist) or Lutasteride (L2) | Degarelix: GnRH Receptor Antagonist; Lutasteride: GnRH Receptor Agonist | • ADT-naïve (exception: neoadjuvant/adjuvant ADT for which the last injection ≥12 months prior to randomization).  
• Pre-existing CVD with at least one of the following:  
  - Myocardial infarction.  
  - Coronary artery stent placement; coronary artery balloon angioplasty; CABG; stent placement or balloon angioplasty to a carotid, iliac, femoral, or popliteal artery; CEA; vascular bypass surgery of the iliac, femoral, or popliteal arteries.  
• Results from an angiogram or CT angiogram that documented at least one vascular stenosis ≥50%.  
• Carotid US results that documented a vascular stenosis ≥50%.  
• No brain metastases per prior clinical evaluation.  
• 3-month washout from previous ADT if therapy was received for ≤ 18 months.  
• No previous GnRH analog or other ADT for > 18 months.  
• No previous novel agents or androgen blockade.  
• No prior GnRH agonist or other ADT for > 18 months.  
• Ongoing androgen deprivation.  
• Ongoing androgen deprivation.  
• Confirmed prostate adenocarcinoma without small cell histology.  
• Progression within 6 months prior to screening.  
• Ongoing androgen deprivation.  
• No prior adjuvant therapy (chemotherapy, radiation, or hormonal).  | Pending activation |
| Uchio     | S. Bereta, P. Duffy, K. Corey | UCI 17-48: HERO: A Multinational Phase 3 Randomized, Open-label, Parallel Group Study to Evaluate the Safety and Efficacy of Relugolix in Men with Advanced Prostate Cancer | GnRH Receptor Antagonist | • No previous GnRH analog or other ADT for > 18 months.  
• -3 month washout from previous ADT if therapy was received for ≤ 18 months.  
• No brain metastases per prior clinical evaluation. | Open to accrual |

### PROSTATE CANCER: Castration-Resistant, Metastatic, Symptomatic

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• Progression within 6 months prior to screening.  
• Ongoing androgen deprivation.  
• No prior chemotherapy (including radiation).  
• No prior treatment with a PARP inhibitor, platinum, cyclophosphamide, or mitoxantrone.  
• No prior anti-PARP therapy for mCRPC.  
• No prior radiotherapy.  
• No prior surgery.  
• No prior abiraterone.  | A/D: Open to accrual; B/C: Closed to accrual |
| Uchio     | S. Bereta, P. Duffy, K. Corey | UCI 17-25: A Phase 2, Open-Label, 2-Arm, Response Rate Study of Talazoparib in Men With DNA Repair Defects and Metastatic Castration-Resistant Prostate Cancer Who Previously Received Taxane-Based Chemotherapy and Progressed on at Least 1 Novel Hormonal Ag | PARP Inhibitor | • DNA repair gene defect that may sensitize to PARP inhibition as assessed by a gene mutation biomarker panel.  
• Metastatic disease with measurable soft tissue disease by CT or MRI per RECIST 1.1.  
• Previous treatment with 1-2 chemotherapy regimens including at least 1 taxane-based regimen.  
• Disease progression during previous treatment for mCRPC with at least 1 novel hormonal therapy (enzalutamide and/or abiraterone).  | Open to accrual |
| Uchio     | S. Bereta, P. Duffy, K. Corey | UCI 18-47: A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Talazoparib with Background Enzalutamide in Metastatic Castration-Resistant Prostate Cancer with DNA Damage Repair Deficiencies (TALAPRO-2) | PARP Inhibitor | • Asymptomatic or mildly symptomatic mCRPC.  
• No previous novel agents or androgen blockade. | Pending activation |

### PROSTATE CANCER: Observational

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Steven Bereta: 506-7887 (pager)  
Katelyn Corey: 509-2170 (Ph)  
Dorothy Chang: 506-1215 (pager)  
Linda Huynh: 456-7354 (Ph)  
Phillip Duffy: 456-6801 (Ph)  
Renai Yoon: 456-8176 (Ph)  
April 2019
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<tr>
<td>Ahlering</td>
<td>L. Huynh</td>
<td>UCI 98-41 Outcomes and Assessment of Prostate Cancer at UCIMC</td>
<td>Radical Prostatectomy</td>
<td>N/A</td>
<td>Open to accrual</td>
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<tr>
<td>Ahlering</td>
<td>L. Huynh</td>
<td>UCI 17-07: Patient Reported Outcomes via Online Questionnaire (PROVOQ): Post-Radical Prostatectomy Outcome Assessment</td>
<td>Online questionnaire</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
</tbody>
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| Uchio       | S. Bereta, P. Duffy, K. Corey | UCI 17-40: Precision Medicine for Early Prostate Cancer: Integrating Biological and Patient Complexity Variables to Predict Treatment Response | N/A                        | • All men with early prostate cancer without extracapsular extension or regional/distant metastasis.  
  • PSA <50ng/mL  
  • Patient has had a prostate bx within 3 months | Open to accrual |
| Uchio       | S. Bereta, P. Duffy, K. Corey | UCI 18-36: Long-Term Prospective Registry to Evaluate Treatment Decisions and Clinical Outcomes in Patients with Favorable Intermediate-Risk Localized Prostate Cancer Following Cell Cycle Progression (CCP) Testing (Prolaris® Test) | N/A                        | • Favorable intermediate-risk disease per NCCN:  
  -Predominant Gleason grade 3; AND  
  -Percentage of positive cores <50%; AND  
  -No more than 1 of the NCCN intermediate-risk factors:  
  -Gleason grade 7  
  -T2b-T2c  
  -PSA 10-20 ng/mL | Pending activation |
| Ahlering    | L. Huynh| UCI 00-55: Retrospective Evaluation of Prostate Cancer Clinical and Pathological Outcomes | Radical Prostatectomy      | N/A                                                                                     | Open to accrual|
| Uchio       | S. Bereta, P. Duffy, K. Corey | UCI 16-84: A Phase III, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study Of Atezolizumab (Anti−PD-L1 Antibody) As Adjuvant Therapy In Patients With Renal Cell Carcinoma At High Risk Of Developing Metastasis Following Nephrectomy | Anti-PD-L1                 | • pT3a+ RCC s/p nephrectomy.  
  • Negative surgical margin.  
  • Absence of residual disease and absence of metastasis. | Open to accrual |
| Uchio       | S. Bereta, P. Duffy, K. Corey | UCI 18-131: A Phase III Randomized Open Label Study to Compare NKTR-214 Combined with Nivolumab to the Investigator’s Choice of Sunitinib or Cabozantinib in Patients with Previously Untreated Advanced Renal Cell Carcinoma | Anti-PD-L1                 | • pT3a+ RCC s/p nephrectomy.  
  • Negative surgical margin.  
  • Absence of residual disease and absence of metastasis. | Pending activation |
| Landman     | R. Yoon | UCI 11-19: Evaluation of Peritumoral Renal Adipose Tissue to Renal Cancer Aggressiveness | Analysis of renal fat and renal tissue samples | • Adult undergoing a radical/simple/partial nephrectomy. | Open to accrual |
| Landman     | R. Yoon | UCI 13-03: Office-Based Percutaneous Ultrasound-Guided Renal Biopsy | Prospective database of renal biopsy patients | • Cannot be pregnant.  
  • No coagulopathy or other bleeding disorder.  
  • No active urinary tract infections.  
  • No requirement to take, Aspirin or Coumadin. | Open to accrual |

**PROSTATE CANCER: Retrospective Review**

**RENAI CANCER: Adjuvant**

**RENAI CANCER: Non-Treatment**

**References**

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