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</tr>
</thead>
</table>
| Ahlering/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 | UCI 19-11: SIMCAP (Surgery in Metastatic Carcinoma of Prostate): 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 Metastatic Prostate Cancer | Cytoreductive Prostatectomy | | Open to accrual |
| Uchio/S. Bereta, P. Duffy | 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 Lutropin | Degarelix: GnRH Receptor Antagonist; Lutropin: 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%.  
-ABPI < 0.9 at any time point before randomization. | Open to accrual |
| Uchio/S. Bereta, P. Duffy | UCI 18-118: A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Apalutamide in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Who Are Candidates for Radical Prostatectomy (PROTEUS) | AR Inhibitor | | Open to accrual |
### Genitourinary

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</thead>
<tbody>
<tr>
<td><strong>Ahlering L. Huynh</strong></td>
<td></td>
<td>UCI 98-41: Outcomes and Assessment of Prostate Cancer at UCIMC</td>
<td>Radical Prostatectomy</td>
<td>N/A</td>
<td>Suspended (IRB Expired)</td>
</tr>
<tr>
<td><strong>Ahlering L. Huynh</strong></td>
<td></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>
<tr>
<td><strong>Uchio S. Bereta, P. Duffy</strong></td>
<td></td>
<td>UCI 17-40: Precision Medicine for Early Prostate Cancer: Integrating Biological and Patient Complexity Variables to Predict Treatment Response</td>
<td>N/A</td>
<td>• Favorable intermediate-risk disease per NCCN: - Predominant Gleason grade 3; AND - Percentage of positive cores &lt;50%; AND - No more than 1 of the NCCN intermediate-risk factors: - Gleason grade 7 - T2b-T2c - PSA 10-20 ng/mL</td>
<td>Open to accrual</td>
</tr>
<tr>
<td><strong>Uchio S. Bereta, P. Duffy</strong></td>
<td></td>
<td>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)</td>
<td>N/A</td>
<td>• Favorable intermediate-risk disease per NCCN: - Predominant Gleason grade 3; AND - Percentage of positive cores &lt;50%; AND - No more than 1 of the NCCN intermediate-risk factors: - Gleason grade 7 - T2b-T2c - PSA 10-20 ng/mL</td>
<td>Open to accrual</td>
</tr>
<tr>
<td><strong>Uchio S. Bereta, P. Duffy</strong></td>
<td></td>
<td>UCI 19-48: Study of Prostate Ablation Related Energy Devices (SPARED) Registry</td>
<td>N/A</td>
<td>• Favorable intermediate-risk disease per NCCN: - Predominant Gleason grade 3; AND - Percentage of positive cores &lt;50%; AND - No more than 1 of the NCCN intermediate-risk factors: - Gleason grade 7 - T2b-T2c - PSA 10-20 ng/mL</td>
<td>Pending activation</td>
</tr>
<tr>
<td><strong>Ahlering L. Huynh</strong></td>
<td></td>
<td>UCI 00-55: Retrospective Evaluation of Prostate Cancer Clinical and Pathological Outcomes</td>
<td>Radical Prostatectomy</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
<tr>
<td><strong>TBD</strong></td>
<td></td>
<td>UCI 19-95: A Randomized, Double-Blind, Controlled Phase III Study of Cabozantinib in Combination with Nivolumab and Ipilimumab versus Nivolumab and Ipilimumab in Subjects with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma of Intermediate or Poor Risk</td>
<td>Cabo: RTK inhibitor; Nivo: IgG4 kappa Ab; Ipi: IgG1 kappa Ab</td>
<td>• Adult undergoing a radical/simple/partial nephrectomy.</td>
<td>Pending activation</td>
</tr>
<tr>
<td><strong>Uchio S. Bereta, P. Duffy</strong></td>
<td></td>
<td>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</td>
<td>Prodrug of conjugated immunotherapy cytokine that binds to the IL-2 receptor</td>
<td>• Adult undergoing a radical/simple/partial nephrectomy.</td>
<td>Pending activation</td>
</tr>
</tbody>
</table>

**PROSTATE CANCER: Observational**

**PROSTATE CANCER: Retrospective Review**

**RENALE CANCER: Adjuvant**

**RENALE CANCER: Non-Treatment**
<table>
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<tr>
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<tbody>
<tr>
<td>Landman</td>
<td>R. Yoon</td>
<td>UCI 13-03: Office-Based Percutaneous Ultrasound-Guided Renal Biopsy</td>
<td>Prospective database of renal biopsy patients</td>
<td>• Cannot be pregnant.&lt;br&gt;• No coagulopathy or other bleeding disorder.&lt;br&gt;• No active urinary tract infections.&lt;br&gt;• No requirement to take, Aspirin or Coumadin.</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 15-77: A Phase II Clinical Trial to study the efficacy and safety of Pembrolizumab (MK-3475) in subjects with high risk non-muscle invasive bladder cancer (NMIBC) unresponsive to Bacillus Calmette-Guerin (BCG) therapy</td>
<td>Anti PD-1/PD-L1/PD-L2</td>
<td>• BCG refractory.&lt;br&gt;• Confirmed diagnosis of high risk non-muscle-invasive (T1, High Grade Ta and/or CIS) bladder TCC.&lt;br&gt;• No muscle invasive (T2-T4), locally advanced non-resectable, or metastatic urothelial carcinoma.&lt;br&gt;• ≥9 Doses of BCG within the last 9 months.</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-53: A Phase III, Randomized, Comparator-Controlled Clinical Trial to Study the Efficacy of Pembrolizumab (MK-3475) in Combination with Bacillus Calmette-Guerin (BCG) in Participants with Intermediate or High Risk Non-Muscle Invasive Bladder Cancer</td>
<td>Anti PD-1/PD-L1/PD-L2</td>
<td>• BCG refractory.&lt;br&gt;• Failed one prior course of BCG.&lt;br&gt;• Confirmed diagnosis of high risk non-muscle-invasive (T1, High Grade Ta and/or CIS) bladder TCC.&lt;br&gt;• No muscle invasive (T2-T4), locally advanced non-resectable, or metastatic urothelial carcinoma.&lt;br&gt;• ≥9 Doses of BCG within the last 9 months.</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Hugen</td>
<td>C. Pichon/A. Montes</td>
<td>SWOG S1602: A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naive High-Grade Non-Muscle Invasive Bladder Cancer</td>
<td>Granulomatous reaction inducer</td>
<td>• Histologically proven Ta, CIS or T1 stage high-grade bladder urothelial cell carcinoma (per 2004 WHO/ISUP classification) ≤90 days prior to registration.&lt;br&gt;• Removal of grossly visible papillary tumors or cystoscopy confirming no grossly visible papillary tumors ≤30 days prior to registration.&lt;br&gt;• If has T1 disease, have resection confirming ≤T1 disease ≤90 days prior to registration.&lt;br&gt;• No prior intravesical BCG or intradermal BCG therapy.&lt;br&gt;• PPD negative ≤90 days prior to registration.</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Mar</td>
<td>D. Chang/A. Montes</td>
<td>UCI 17-18: A Single-Arm, Open-Label, Multicenter Study of Enfortumab Vedotin (ASG 22CE) for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer who Previously Received Immune Checkpoint Inhibitor (CPI) Therapy</td>
<td>Nectin-4 targeted mAb linked to MMAE</td>
<td>• Confirmed urothelial carcinoma (squamous differentiation or mixed cell types).&lt;br&gt;• Prior CPI treatment in locally advanced or metastatic setting.&lt;br&gt;• Cohort 2: Platinum-naive (includes platinum treatment in the adjuvant/neoadjuvant setting without progression ≤12 months of completion) and cisplatin ineligible [impaired renal function (CrCl 30 to &lt;60 mL/min) or a hearing loss of ≥25 dB at two contiguous frequencies].&lt;br&gt;• PD or recurrence during/following most recent therapy.&lt;br&gt;• Measureable disease per RECIST v1.1.</td>
<td>Cohort 2: Open to accrual</td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-102: A Phase III, Randomized, Study of Neoadjuvant Chemotherapy Alone versus Neoadjuvant Chemotherapy Plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab and BMS-986205 in Participants with Muscle Invasive Bladder Cancer</td>
<td>PD-1</td>
<td>• T2 or T3 TCC/bladder.&lt;br&gt;• Surgical candidate for cystectomy.</td>
<td>Pending activation</td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-130: A Phase II Open-Label Study of NKTR-214 in Combination with Nivolumab in Cisplatin Ineligible, Locally Advanced or Metastatic Urothelial Cancer</td>
<td>PD-1</td>
<td>• T2 or T3 TCC/bladder.&lt;br&gt;• Surgical candidate for cystectomy.</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-132: A Phase III, Randomized, Study of Neoadjuvant and Adjuvant Nivolumab Plus NKTR-214, Versus Nivolumab Alone Versus Standard of Care in Participants with Muscle-Invasive Bladder Cancer (MIBC) Who Are Cisplatin Ineligible</td>
<td>PD-1</td>
<td>• T2 or T3 TCC/bladder.&lt;br&gt;• Surgical candidate for cystectomy.</td>
<td>Pending activation</td>
</tr>
</tbody>
</table>

**UROTHELIAL CANCER: Non-Metastatic**

**UROTHELIAL CANCER: Locally Advanced or Metastatic**

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**February 2020**
### Genitourinary

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<tr>
<td><strong>UCI 15-18: A Dose-Escalation and Dose-Expansion Study of Enfortumab Vedotin (ASG-22CE) in Combination with Pembrolizumab and/or Chemotherapy for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer</strong></td>
<td>Nectin-4 targeted mAB linked to MMAE</td>
<td>• Cohort K [EV Mono/EV+Pembro]: Cis ineligible due to at least 1 of the following: ECOG 2, CrCl ≥30 and &lt;60 mL/min, hearing loss/dysfunction, age, and/or allergy to cis. -Must not have received prior systemic treatment for locally advanced or metastatic disease. -May not have previously received adjuvant/neoadjuvant platinum-based therapy within 12 months prior to randomization. -Confirmed locally advanced (unresectable with curative intent)/metastatic UC (squamous differentiation or mixed cell types). -PD or recurrence during/following most recent therapy. -Measureable disease per RECIST v1.1. • Cohort H [EV Mono]: Cis ineligible due to at least 1 of the following: ECOG 2, CrCl ≥30 and &lt;60 mL/min, hearing loss/dysfunction, age, and/or allergy to cis. -No prior systemic treatment, chemoradiation, or radiation therapy for MIUC. -May have received prior intravesical BCG/intravesical chemo for NMIBC. -Confirmed bladder MIUC (mixed cell types eligible if predominantly UC: &gt;50%; neuroendocrine tumors are ineligible regardless of component percentage). -ct2-T4a by TURBT within 90 days prior to first dose and N0M0 by CT/MRI within 4 weeks of enrollment; mpMRI of the bladder is allowed.</td>
<td>Cohorts K/H: Open to accrual</td>
<td></td>
</tr>
<tr>
<td><strong>UCI 19-09: A Phase III, Randomized, Double-blind Study to Compare the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Lenvatinib (E7080/MK-7902) Versus Pembrolizumab and Matching Placebo as First Line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma in Cisplatin-Ineligible Participants Whose Tumors Express PD-L1, and in Participants Ineligible for Any Platinum-containing Chemotherapy Regardless of PD-L1 Expression (LEAP-011)</strong></td>
<td>Anti PD-1/PD-L1/PD-L2</td>
<td>• Cohort 5 (Ibrutinib monotherapy): Prior CPI. • Cohort 6 (Ibrutinib + Pembro): -(Untreated setting-Pembro Eligible) Cisplatin ineligible with PDL-1 (CPS) score ≥ 10 without prior treatment. -(Relapsed setting-CPI naïve) Progression on platinum chemotherapy, or ≤12 months of neo or adjuvant therapy with a platinum chemotherapy. -No prior CPI. -Lack of recovery from previous therapeutic radiation (persistence of Grade ≥2 radiation-related toxicity) or planned radiation therapy during the study period.</td>
<td>Cohort 6: Open to accrual</td>
<td></td>
</tr>
<tr>
<td><strong>UCI 19-23: A Phase Ib/II Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal and Genitourinary Tumors</strong></td>
<td>BTK inhibitor</td>
<td>• Histologically proven T2-T4a NO M0 UC of the bladder within 70 days of randomization (small cell carcinoma excluded). • Patients must undergo a TURBT within 70 days prior to randomization. • ECOG 0-2. • No diffuse CIS based on cystoscopy and biopsy. • No prior pelvic radiation. • No prior treatment for MIIBC including neoadjuvant chemotherapy for current tumor.</td>
<td>Open to accrual - only at Orange</td>
<td></td>
</tr>
<tr>
<td><strong>SWOG S1806: Phase III Trial of Concurrent Chemoradiation with or without Atezolizumab for Localized Muscle Invasive Bladder Cancer</strong></td>
<td>Anti PD-1/PD-L1</td>
<td>• Newly diagnosed or under surveillance (within 2 years) for recurrent bladder cancer or have microscopic and macroscopic hematuria. • No urinary diversions. • No recent percutaneous or endoscopic procedures for upper tract diseases. • No ureteral stents placed for upper urinary tract obstruction. • No recent trauma in kidney, bladder or perineal area.</td>
<td>Open to accrual</td>
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### UROTHELIAL CANCER: Non-Treatment

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<tr>
<td><strong>Landman M. Wu, R. Yoon</strong></td>
<td>UC15-22: Electro-Phage and Colorimetric Aptamer Sensors for Clinical Staging and Monitoring of Bladder Cancer</td>
<td>Analysis of patient urine samples</td>
<td>• Newly diagnosed or under surveillance (within 2 years) for recurrent bladder cancer or have microscopic and macroscopic hematuria. • No urinary diversions. • No recent percutaneous or endoscopic procedures for upper tract diseases. • No ureteral stents placed for upper urinary tract obstruction. • No recent trauma in kidney, bladder or perineal area.</td>
<td>Open to accrual</td>
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</tbody>
</table>

**BASKET TRIALS**
<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Principal Investigator(s)</th>
<th>Study Details</th>
<th>Number of Participants</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-64: An Open-Label, Multicenter, Phase 1/2 Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors</td>
<td>Oncolytic immunotherapy with PD-L1 inhibitor</td>
<td>Pending activation</td>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Uchio</td>
<td>S. Bereta, P. Duffy</td>
<td>UCI 18-103: Blood Sample Collection to Evaluate Biomarkers in Subjects with Untreated Solid Tumors</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Bota</td>
<td>M. Dandekar</td>
<td>ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)</td>
<td>Varies per mutation</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Bota</td>
<td>M. Tharani</td>
<td>SWOG 51609 DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Bota)</td>
<td>18: Squamous cell carcinoma variants of the genitourinary (GU) system, 19: Spindle cell carcinoma of kidney, pelvis, ureter, 50: PD-L1 amplified tumors (NEW), 53: Treatment-emergent small-cell neuroendocrine prostate cancer (t-SCNC) (NEW)</td>
<td>Suspended</td>
</tr>
<tr>
<td>Parajuli</td>
<td>D. Richard/J. Spolarich</td>
<td>UCI 18-87: Treatment Resistance Following Anti-Cancer Therapies (Translate)</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Bristow</td>
<td>TBD</td>
<td>UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California</td>
<td>N/A</td>
<td>Pending activation</td>
</tr>
<tr>
<td>Lee</td>
<td>C. Duong</td>
<td>UCI 18-110: A Phase II, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib in Participants with Previously Treated Locally Advanced/Metastatic or Surgically Unresectable Solid Tumor Malignancy Harboring Activating FGFR 1-3 inhibitor</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Du</td>
<td>O. Quines</td>
<td>UCI 19-2B: A Phase II/III, Open-Label, Multicenter Dose Escalation and Expansion Study of the Combination of RMC-4630 and Cobimetinib in Adult Participants with Relapsed/Refractory Solid Tumors with Specific Genomic Aberrations</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Ejadi</td>
<td>J. Nguyen (STEM Cell Center)</td>
<td>UCI 19-3B: A Phase I/II, Open-Label First-in-Human Study of the Safety, Tolerability, and Feasibility of Gene-Edited Autologous NeoTCT-T Cells (NeoTCT-P1) Administered as a Single Agent or in Combination with Anti-PD-1 to Patients with Locally Advanced or Metastatic Solid Tumors</td>
<td>N/A</td>
<td>Open to accrual</td>
</tr>
</tbody>
</table>

- History of advanced or metastatic non-neurological solid tumors, who have progressed on/cannot tolerate standard therapy, or for which there is no standard therapy.
- At least one measurable and injectable (including use of image-guided injection) tumor of ≥ 1 cm in longest diameter (or shortest diameter for lymph nodes).
- Phase 2 only:
- -Diagnosis of stage IIIb-IV unresectable melanoma, metastatic MSI-H or metastatic dMMR, locally advanced or metastatic UBC or NSMC (not considered treatable with surgical excision), for whom PD-1 directed therapy is indicated according to a current approved label or who have previously received PD1/L1 directed therapy.
- -Must be eligible to receive nivolumab according to product label, or have exhausted/become intolerant to/refuse/currently available therapies for melanoma.
- Cannot have previous oncolytic therapy.
- No brain metastases, interstitial lung disease, of severe hypersensitivity to another monoclonal antibody.
- Cannot require intermittent or chronic use of systemic (oral/IV) anti-virals with known anti-herpetic activity (e.g. acyclovir).
- M. Dandekar

- FGFR 1-3 inhibitor
- Untreated solid tumors.
- ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)
- UCI 18-87: Treatment Resistance Following Anti-Cancer Therapies (Translate)
- Positive for specific mutations.
Ou K. Inocencio

UCI 19-64: A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors

- Must have received prior standard therapy appropriate for their tumor type and stage of disease, or in the opinion of the Investigator, would be unlikely to tolerate or derive clinically meaningful benefit from appropriate standard of care therapy.
- Locally-advanced unresectable or metastatic solid tumor malignancy with documented NRG1 gene fusion, identified through molecular assays such as PCR, next generation sequencing-based assays [DNA or RNA], or FISH as routinely performed at CLIA or other similarly-certified laboratories.

Open to accrual

Genitourinary