UCI Chao Family Comprehensive Cancer Center

# Genitourinary

| TESTICULAR CANCER: Observational | | | | | |
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| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Hugen | A. Gilbert | S1823: A Prospective Observational Cohort to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors | N/A | • Newly diagnosed germ cell or testicular non-germ cell tumor within 42 days of study registration. | Open to accrual |
| **TESTICULAR CANCER: Supportive Care** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Hoyt | TBD | UCI 20-59: a Biobehavioral Intervention to Reduce Adverse Outcomes in Young Adult Testicular Cancer Survivors | N/A | • Completion of chemotherapy for testis cancer within 2 years prior to consent.<br>• A score of < 1.8 on the goal navigation scale or < 0.6 on the goal facility scale of the CAYA or >4 on the Distress Thermometer.<br>• No lifetime history of psychiatric of cognitive disturbance as per self-report or medical record.<br>• No self-reported medical conditions that affect the immune system and would confound immune evaluation.<br>• Not a regular smoker (daily use). | Pending activation |
| **PROSTATE CANCER: Surgical Candidates** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Lee | L. Huynh, E. Huang | 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 | • Histologically proven adenocarcinoma of the prostate.<br>• Evidence of metastasis by MRI/CT scan, bone scan, or histologic confirmation.<br>• Clinical stage M1a (distant lymph node positive), or M1b (bone metastasis).<br>-If solitary lesion, metastasis confirmed with either biopsy or two independent imaging modalities (i.e. CT and PET, bone scan and MRI, modality at the discretion of the treating physician).<br>• No previous local therapy for prostate cancer.<br>• Started ADT no longer than 6 months prior to randomization.<br>• Patients who have chemotherapy, radiotherapy or oral antifungal agents (Ketoconazole, itraconazole, fluconazole) within 3 weeks prior to entering the study or those who have not recovered (e.g. back to baseline or grade 1) from adverse events due to agents administered more than 3 weeks earlier are excluded. | Suspended |
| Uchio | TBA | UCI-21-136: Pivotal Study of the NanoKnife System for Ablation of Prostate Tissue in an Intermediate-Risk Patient Population | | | Pending activation |
| **PROSTATE CANCER: Hormone-Sensitive** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Rezazadeh | B. Robertson | UCI 20-137: A Phase III Double-Blind, Randomized, Placebo-Controlled Study Assessing the Efficacy and Safety of Capivasertib + Abiraterone Versus Placebo + Abiraterone as Treatment for Patients with De Novo Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Characterised by PTEN Deficiency (CAPItello-281) | Capivasertib: AKT kinase inhibitor; Abiraterone: androgen biosynthesis inhibitor | • Histologically confirmed de novo (within 3 months of randomization) metastatic hormone-sensitive prostate adenocarcinoma (small-cell tumors not eligible).<br>• PTEN deficiency<br>• Asymptomatic or mildly symptomatic<br>• Ongoing ADT with GnRH analogue or LHRH antagonist, or bilateral ochiectomy. Duration of ongoing ADT is 0 to a maximum of 3 months prior to randomization. | Open to accrual |

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| Uchio | P. Duffy | UCI 20-146: A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone (AA-P) and ADT versus Abiraterone Acetate and Prednisone and ADT in Subjects with Metastatic Castration Sensitive Prostate Cancer (mCSPC) with DNA-Repair Gene | Niraparib: PARP inhibitor; Abiraterone: androgen biosynthesis inhibitor | • Diagnosis of prostate adenocarcinoma.<br>• Metastatic disease documented by at least 1 bone lesion.<br>• Must have at least 1 deleterious germline or somatic HRR gene mutations listed: BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, PALB2, RAD51B, RAD54L.<br>• ADT must have started ≥ 14 days prior to randomization and willing to continue through the treatment phase. Participants who start a GnRH agonist ≤ 28 days prior to randomization will be required to take 1st gen anti-androgen for ≥ 14 days and discontinued prior to randomization.<br>• No small cell ductal or neurendocrine carcinoma of the prostate.<br>• No prior treatment with a PARP inhibitor, AR-targeted therapy, immunotherapy, or radiopharmaceutical agents with the exception of only 30 days of AA-P.<br>• No bisphosphonate or denosumab for bone metastasis ≤ 28 days before randomization.<br>• No history of adrenal dysfunction.<br>• No active malignancies other than the disease being treated under the study with the exceptions of:<br>-Non-muscle invasive bladder cancer<br>-Skin cancer treated ≤ 24 months and considered completely cured<br>-Breast cancer - adequately treated lobular carcinoma in situ or ductal carcinoma in situ<br>-Malignancy that is considered cured with minimal risk of recurrence<br>• No history of or current MDS/AML. | Open to accrual |
| Uchio | TBA | UCI 21-130: Open-Label Study of Androgen Receptor Inhibition with dArolutamide Plus Androgen Deprivation Therapy (ADT) Versus ADT in Men with Metastatic Hormone-Sensitive Prostate Cancer Using an External Control Arm (ARASEC) | Androgen Receptor Inhibition | | Pending activation |
| **PROSTATE CANCER: Castration-Resistant** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Mar | M. Popal | UCI 16-76: Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365) | Anti PD-1/PD-L1/PD-L2 | • Confirmed prostate adenocarcinoma without small cell histology.<br>• Progression within 6 months prior to screening.<br>• Ongoing androgen deprivation.<br>• No prior radium/radiopharmaceutical treatment. | Pembro retreatment only |
| Rezazadeh | M. Popal | UCI 20-10: A Phase III Randomized, Double-Blind Study of Nivolumab or Placebo in Combination with Doxetaxel, in Men with Metastatic Castration-Resistant Prostate Cancer | Nivolumab: Anti-PD-1 mAb | • Stage IV prostate adenocarcinoma without small cell features.<br>• Progression as per PCWG3 criteria within 6 months prior to screening.<br>• Chemotherapy-naïve and have progressed or intolerant after 1-2 novel antiandrogen therapies [NATs] in the recurrent non-metastatic setting and/or 1 prior NAT in the metastatic setting.<br>• Prior docetaxel for metastatic castration-sensitive is allowed if ≥12 months elapsed from last dose of docetaxel.<br>• No prior anti-PD-1/PD-L1/PD-L2/CTLA-4 Ab or any other Ab/drug targeting T-cell co-stimulation or checkpoint pathways. | Open to accrual |
| Uchio | H. Dimasuay | UCI 20-62: A Phase Ib/II, Open-Label, Randomized Platform Study Evaluating the Efficacy and Safety of AB928-Based Treatment Combinations in Patients with Metastatic Castrate Resistant Prostate Cancer | AB928: A2aR and A2rR antagonist | | Open to accrual |

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| Rezazadeh | A. Gilbert | UCI 20-181: SPLASH: Study Evaluating Metastatic Castrate Resistant Prostate Cancer Treatment Using Lu-PNT2002 PSMA Therapy After Second-line Hormonal Treatment | Lu-PNT2002: PSMA-targeted radioligand | * Histological, pathological, and/or cytological confirmation of adenocarcinoma of the prostate<br>* Evidence of progressive mCRPC at the time of consent (PSA, soft tissue, or bone disease progression).<br>* Progression on previous treatment with one ARAT<br>* No prior r treatment for prostate cancer ≤28 days prior to randomization ( except first line local, ARAT, LHRH, or non-radioactive bone targeted agents.<br>* Prior treatment with systemic radionuclides, immuno-therapy, except for sipuleucel-T, PSMA-targeted radioligand therapy, PARP inhibitor for prostate cancer.<br>* No major surgery ≤30 days prior to randomization | Open to accrual |
| Rezazadeh | D. Huttar | UCI 20-138: A Phase I/II, Open-Label, Dose Escalation, and Cohort Expansion Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARV-110 in Patients with Metastatic Castration Resistant Prostate Cancer | ARV-110: AR protein degrader | <u>Part B - Phase 2 Cohort Expansion</u><br>• Testosterone <50 ng/dL<br>• 1-2 prior second generation anti-androgen agents for CRPC.<br>• Subgroup 1: Tumors harboring AR T878 and/or H875 mutations.<br>-At most 1 chemotherapy regimen in CSPC and CRPC settings.<br>• Subgroup 4: Less pre-treated group.<br>-Received only 1 prior AR second generation therapy either as treatment for CSPC or CRPC and no more than 1 regimen in CRPC setting.<br>-No prior chemotherapy.<br>• Results of tumor DNA sequence analysis, including AR gene, known prior to initiation of treatment within 3 months of enrollment. | Part B Exp Subgroups 1/4: Open to accrual |
| Rezazadeh | A. Gilbert | UCI 21-07: A Master Protocol Evaluating the Safety and Efficacy of Therapies for Metastatic Castration-Resistant Prostate Cancer (mCRPC) | AMG 160: T-cell engager; AMG 404: PD-1 inhibitor; Enzalutamide: antiandrogen; Abiraterone: antiandrogen | • Histologically or cytologically confirmed mCRCP adenocarcinoma of the prostate without pure neuroendocrine differenciation or small cell.<br>• No prior aviraterone or treatment with a taxane.<br>• Must have bilateral orchiectomy or on continueous ADT with a gonadotropin releasing hormone agonist or antagonist.<br>• Total serum testosterone ≤ 50 ng/dL. | Open to accrual |
| Uchio | S. Bereta | UCI 21-79: Randomized, Active-Controlled, Phase III Study of VERU-111 for the Treatment of Metastatic Castration-Resistant Prostate Cancer in Patients who have Failed Prior Treatment with at Least One Androgen Receptor Targeting Agent (VERACITY) | VERU-111: microtubule fragmentation | | Pending activation |
| Rezazadeh | TBA | UCI 21-83: PSMAddition: An International Prospective Open-Label, Randomized, Phase III Study Comparing 177Lu-PSMA-617 in Combination with Standard of Care, Versus Standard of Care Alone, in Adult Male Patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC) | Lu-PSMA-617: PSMA-targeted radioligand | | Pending activation |
| Mar | M. Le | ETCTN-10301: A Phase I and Randomized Phase II Trial of Radium-223 Dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) | Radium-233: Alpha particle radiation; M3814: DNA-PK inhibitor; Avelumab: Anti-PD-L1 | • Testosterone <20 ng/dL<br>• Progressive CRPC with ≥2 skeletal metastases identified by bone scan. ≥1 LN metastases allowed (LN must measure <3 cm in the longest dimension). Visible visceral organ metastases are not allowed.<br>• Progression after abiraterone, enzalutamide, docetaxel, or other secondary hormonal therapy. There is no maximum number of prior therapies.<br>• No prior therapy with radionuclides, hemibody external radiation, or systemic radiotherapy with radioisotopes.<br>• Able to discontinue medications that are potent inhibitors, inducers or sensitive substrates of CYP3A4/5 or CYP2C19.<br>• Able to discontinue concomitant H2 blockers or PPIs. | Ph 1: Open to accrual (slot resevation required) |
| **PROSTATE CANCER: Non-Treatment** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Ahlering | B. Morales | UCI 98-41 Outcomes and Assessment of Prostate Cancer at UCIMC | Radical Prostatectomy | | Open to accrual *IRB Expried |
| Ahlering | E. Huang; R. Ceja | UCI 17-07: Patient Reported Outcomes via Online Questionnaire (PROVOQ): Post-Radical Prostatectomy Outcome Assessment | Online questionnaire | | Open to accrual |

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| Uchio | N. Oune | UCI-17-40: Precision Medicine for Early Prostate Cancer: Integrating Biological and Patient Complexity Variables to Predict Treatment Response | Questionnaire | *Adult males aged 18 years to 79 years old<br>* Diagnosis of prostate cancer, clinical stage T1 or T2, with no evidence of metastasis<br>* PSA less than 50 ng/mL<br>*Not previously undergone any treatment for prostate cancer<br>*Diagnosis of prostate cancer less than 6 months before baseline visit | Open to accrual |
| Bristow | D. Garcia; A. Vargas | UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California | N/A | • Adults diagnosed with prostate cancer ≥18 and over. | Pending activation |
| Uchio | S. Bereta | UCI 19-48: Study of Prostate Ablation Related Energy Devices (SPARED) Registry | | | Pending activation |
| Ahlering | E. Huang | UCI 00-55: Retrospective Evaluation of Prostate Cancer Clinical and Pathological Outcomes | N/A | | Open to accrual |
| **RENAL CANCER: Adjuvant** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Rezazadeh | B. Robertson | UCI 20-123: An Open-Label, Randomized, Phase III Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-Line or Third-Line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy | Belzutifan: HIF-2α antagonist; Lenvatinib: kinase inhibitor; Cabozantinib: tyrosine kinase inhibitor | • Histologically confirmed unresectable, locally advanced/metastatic RCC with clear cell component with or without sarcomatid features.<br>• Has experienced disease progression on or after first or second line systemic therapy with an anti-PD-1/L1 therapy for locally advanced/metastatic RCC, but no more than one anti-PD-1/L1 therapy.<br>• No more than 2 prior systemic regimens for locally advanced/metastatic RCC. | Open to accrual |
| Freuhauf | B. Robertson | UCI 20-124: An Open-Label, Randomized Phase III Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with MK-6482 and Lenvatinib (MK-7902), or MK-1308A in Combination with Lenvatinib, versus Pembrolizumab and Lenvatinib, as First Line Treatment in Participants with Advanced Clear Cell Renal Cell Carcinoma (ccRCC) | MK-6482: HIF-2α inhibitor; Pembrolizumab: anti-PD-1; Lenvatinib: kinase inhibitor; MK-1308A: anti-CTLA4 and anti-PD-1 | • Histologically confirmed unresectable, locally advanced/metastatic RCC with clear cell component with or without sarcomatoid features.<br>• No prior systemic treatment for ccRCC.<br>• No other active malignancy. | Open to accrual |
| **RENAL CANCER: Non-Treatment** | | | | | |
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| Landman | R. Yoon | UCI 13-03: Office-Based Percutaneous Ultrasound-Guided Renal Biopsy | Prospective database | • No coagulopathy or other bleeding disorder.<br>• No active urinary tract infections.<br>• No requirement to take, Aspirin or Coumadin. | Open to accrual |
| **UROTHELIAL CANCER: Non-Muscle Invasive** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Landman | R. Yoon | UCI-15-22: Electro-Phage and Colorimetric Aptamer Sensors for Clinical Staging and Monitoring of Bladder Cancer | | | Open to accrual<br>*IRB Expried |
| Uchio | P. Duffy | 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 (KEYNOTE-676) | Anti PD-1/PD-L1/PD-L2 | • BCG refractory.<br>• Failed one prior course of BCG.<br>• Confirmed diagnosis of high risk non-muscle-invasive (T1, High Grade Ta and/or CIS) bladder TCC.<br>• No muscle invasive (T2-T4), locally advanced non-resectable, or metastatic urothelial carcinoma.<br>• ≥9 Doses of BCG within the last 9 months. | Open to accrual |
| Uchio | P. Duffy | 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 | NKTR-214: CD122-based agonist; Nivo: Anti-PD1 | • TURBT confirming MIBC clinical stage T2-T4, N0M0 within 12 weeks of randomization.<br>• Must obtain PD-L1 status and not receive systemic therapy after the sample was obtained.<br>• No prior treatment for bladder cancer other than TURBT. BCG is permitted if completed at least 6 weeks before study treatment. | Open to accrual |

| UROTHELIAL CANCER: Non-Muscle Invasive | | | | | |
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| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Uchio | P. Duffy | UCI 20-91: A Phase II, Single Arm Study of CG0070 Combined with Pembrolizumab in Patients with Non Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG) | CG0070: engineered oncolytic adenovirus; Pembro: Anti PD-1/PD-L1/PD-L2 | • Pathologically confirmed non muscle invasive bladder cancer with or without Ta/T1 disease.<br>• No upper urinary tract or prostatic uretha malignancy.<br>• BCG refractory.<br>• Ineligible for radical cystectomy or refusal of radical cystectomy.<br>• No prior adenovirus-based cancer therapy.<br>• No prior or intolerance to prior checkpoint inhibitor therapy. | Open to accrual |
| Uchio | S. Bereta | UCI 20-210: A Phase III of CG0070 in Patients with Non-Muscular Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG) | CG0070: engineered oncolytic adenovirus | • Pathologically confirmed BCG unresponsive CIS.<br>• Have all Ta and/T1 disease resected and all CIS resected or fulgurated.<br>• Ineligible for radical cystectomy or refused radical cystectomy. | Open to accrual |
| Uchio | S. Bereta | UCI 21-37: (ENLIGHTED) TRIAL: Multicenter Phase III to Evaluate the Safety and Efficacy of TOOKAD (Padeliporfin) Vascular Targeted Photodynamic Therapy Treatment of Upper Tract Urothelial Cancer | Padeliporfin: vascular disruptor | • New or low-grade, non-invasive UTUC disease.<br>• Up to 2 biopsy-proven sites of low-grade involvement with the largest rumor between 5 mm and 15 mm in diameter, located in the calyces, renal pelvis, or in the ureter of ipsilateral kidney, with an absense of high-grade cells on cytology.<br>• No current high-grade, or muscle invasive urothelial carcinoma of the bladder.<br>• No current or previous CIS in the upper urinary tract.<br>• No history of invasive T2 urothelial cancer in the past 2 years.<br>• No BCG or local chemotherapy in the upper urinary tract within 2 months of enrollment.<br>• No systemic chemotherapy within 2 months of enrollment. | Pending activation |
| Uchio | S. Bereta | UCI 21-41: A Study of Intravesical Enfortumab Vedotin for Treatment of Patients with Non-Muscle Invasive Bladder Cancer | | | Pending activation |
| Uchio | S. Bereta | UCI 21-69: A Phase III, Multi-Center, Randomized Study Evaluating Efficacy of TAR-200 in Combination with Cetrelimab Versus Concurrent Chemoradiotherapy in Participants with Muscle-Invasive Urothelial Carcinoma (MIBC) of the Bladder who are not Receiving Radical Cystectomy | TAR-200: nucleotide analog; Cetrelimab: IgG4 anti-PD-1 | • Histologically confirmed cT2-T4c N0, M0 infiltrating urothelial bladder carcinoma within 90 days of randomization. Squamous cell and transitional cell subtypes allowed.<br>• Ineligible for or elected to not undergo radical cystectomy.<br>• No other active malignancies.<br>• No urothelial carcinoma or histological variant at any site outside of the urinary bladder. Ta/T1/CIS of the upper urinary tract (including renal pelvis and ureter) is allowed if treated with complete nephrourectomy within 24 months.<br>• No intervening intravesical chemotherapy or immunotherapy from the time of most recent TURBT to starting study treatment.<br>• No Prior therapy with anti-PD-1, anti-PD-L2, or with an agent directed to another co-inhibitory T-cell receptor. | Pending activation |
| **UROTHELIAL CANCER: Locally Advanced or Metastatic** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Mar | M. Le | UCI 18-138: 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 | Nectin-4 targeted mAB linked to MMAE | • Cohort L (EV Mono): Cis ineligible due to at least 1 of the following: ECOG 2, GFR ≥30 and <60 mL/min, Gr ≥2 hearing loss, NYHA Class III heart failure.<br>-No prior systemic treatment, chemoradiation, or radiation therapy for MIBC.<br>-May have received prior intravesical BCG/intravesical chemo for NMIBC.<br>-Histologically confirmed MIBC with predominant >50% urothelial histology.<br>-cT2-T4aN0M0 or cT1-T4aN1M0 determined by TURBT ≤90 days prior to the first dose and by CT ≤28 days of enrollment; pT1 disease eligible if has N1 disease on imaging. | Cohorts L: Open to accrual |

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| Mar | M. Popal | UCI 19-143: An Open-Label, Randomized, Controlled Phase III Study of Enfortumab Vedotin in Combination with Pembrolizumab with or without Chemotherapy, versus Chemotherapy Alone in Previously Untreated Locally Advanced or Metastatic Urothelial Cancer | Nectin-4 targeted mAB linked to MMAE | • No prior systemic therapy for locally advanced/metastatic UC except:<br>-Prior neoadjuvant chemo w/ recurrence >12 months from completion of therapy.<br>-Prior adjuvant chemo following cystectomy w/ recurrence >12 months from completion of therapy.<br>• Eligible to receive cis- or carbo-containing chemotherapy, per investigator.<br>-Must be cis-ineligible, and will receive carbo, if subjects meet at least one of the following: GFR <60 but ≥30 mL/min; ECOG 2; Gr ≥2 audiometric hearing loss, NYHA Class III heart failure. | Open to accrual |
| Bota | M. Tharani | UCI 20-180: A Phase II, Two-Arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regiments of a Pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects with Metastatic or Surgically Unresectable Urothelial Cancer with FGFR Genomic Alterations | JNJ-42756493: pan-FGFR tyrosine kinase inhibitor | | Pending activation |
| Rezazadeh | B. Robertson | UCI 21-09: A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer (VOLGA) | Radical cystectomy; Durvalumab: anti PD-1; Tremelimumab: anti CTLA-4; EV: anti nectin-4 | • Histological or cytologically confirmed muscle-invasive TCC of the bladder with clinical stage of T2-4aN1M0 (transitional and mixed transitional/non-transitional/variant cell histologies are accepted).<br>• Medically fit for cystectomy and able to receive neoadjuvant therapy. | Open to accrual |
| Rezazadeh | TBA | UCI 21-152: A Phase II Switch Maintenance Study of MRx0518 and Avelumab in Patients with Unresectable Locally Advanced or Metastatic Urothelial Carcinoma Who Did Not Progress on First-Line Platinum-Containing Chemotherapy | MRx0518: increases CD8+/Treg; Avelumab: anti-PD-1/PD-L1 | | Pending activation |
| Yaacoub | B. Robertson | SWOG S1806: Phase III Trial of Concurrent Chemoradiation with or without Atezolizumab for Localized Muscle Invasive Bladder Cancer | Anti PD-1/PD-L1 | • Histologically proven T2-T4a N0 M0 UC of the bladder within 70 days of randomization (small cell carcinoma excluded).<br>• Patients must undergo a TURBT within 70 days prior to randomization.<br>• ECOG 0-2.<br>• No diffuse CIS based on cystoscopy and biopsy.<br>• No prior pelvic radiation.<br>• No prior treatment for MIBC including neoadjuvant chemotherapy for current tumor. | Open to accrual - only at Orange |
| Mar | M. Le | ETCTN-10100: A Randomized, Phase II Trial to Evaluate the Safety and Efficacy of Eribulin Mesylate in Combination with Atezolizumab Compared to Atezolizumab Alone in Subjects with Locally Advanced or Metastatic Transitional Cell Urothelial Cancer Where Cisplatin-Based Treatment is Not an Option | Eribulin mesylate: antimicrotubule antrineoplastic agent; Atezolizumab: Anti PD-L1 and B7 | • Histologically or cytologically confirmed locally advanced/unresectable and/or metastatic transitional cell urothelial cancer of the reval pelvis, ureter, urinary bladder, or urethra.<br>• PD-L1 status determined centrally by HistogeneX.<br>• May have up to two prior lines of chemotherapy for advanced disease.<br>• No prior treatment with anti-PD-1, or anti-PD-L1 therapeutic antibody or pathway targeting agents or eribulin. | Open to accrual |

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| Rezazadeh | M. Popal | ETCTN-10144: A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma with DNA-Repair Defects | PARP Inhibitor | • Histologically confirmed urothelial carcinoma of the urothelial tract/bladder cancer.<br>• Disease progression during treatment or after the most recent dose of therapy with at least one platinum-based regimen and/or an immune-checkpoint inhibitor.<br>• No prior treatment with olaparib or any other PARP inhibitor.<br>• No myelodysplastic syndrome/acute myeloid leukemia.<br><u>Cohort 1:</u><br>• Have confirmed presence of high TMB or one or more of the following genes: BRCA1, BRCA2, ATM, BAP1, MSH2, PALB2, and BRIP1<br><u>Cohort 2:</u><br>• Have confirmed presence of one or more of the DNA-repair genes tested in the FoundationOne FoundationOne® CDx (F1CDx) panel excluding the ones in cohort 1.<br><u>Cohort 3:</u><br>• Patients without eligible cancer-associated DNA-repair gene mutations will be followed for outcomes and blood collection. | Open to accrual |
| **BASKET TRIALS** | | | | | |
| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Ahlering | L. Huynh | UCI 19-39: Using Virtual Reality (VR) Models for Preoperative Planning | VR models | • Have a prostate, kidney, or liver mass with at least one course of treatment that may be an operation in which the CT scan or MRI would be viewed during surgical planning and during the operation. | Open to accrual |
| Nagasaka | K. Buttigieg | UCI 19-57: A Phase I, Open-Label, Multi-Center, First-In-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0022, A Novel Met/CSF1R/SRC Inhibitor, in Patients with Advanced Solid Tumors Harboring Genetic Alterations In Met | TPX-0022: MET/CSF1R/SRC inhibitor | • Dose escalation: Histological/cytological confirmation of advanced/metastatic solid tumors harboring the genetic MET alteration(s) including exon 14 deletion (METΔex14), amplification, fusion or activating kinase mutation, who are resistant or intolerant. | Open to accrual |
| Ou | K. Buttigieg | 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 | HER2, HER3, NRG1 | • 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.<br>• 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 |
| Nagasaka | K. Buttigieg | UCI 19-111: A Phase I/II Study of TPX-0046, a Novel Oral RET/SRC Inhibitor in ADULT Subjects with Advanced/Metastatic Solid Tumors Harboring Oncogenic RET Fusions or Mutations | RET/SRC Inhibitor | • RET fusions or mutations. | Open to accrual |
| Dayyani | C. Duong | UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimub and/or Chemotherapy in Subjects with Advanced Solid Tumors | Anti-CD39, Anti-PD-1 | • Fresh and/or archival tumor tissue within 45 days of first dose or study treatment.<br>• Weigh ≥ 35 kg.<br>• At least 28 days since lasst dose of chemotherapy or biological therapy or at least 14 days since lsat dose of TKI or high-dose steroid therapy prior to loading/first dose of study treatment.<br>Saftey Lead-In Cohort 2:<br>• Histologically or cytologically confirmed adenocarcinoma of the prostate.<br>• PSA less than 50 ng/dL while on androgendeprivation therapy.<br>• Radiographic metastatic disease and disease progression on recent prior systemic regimen.<br>• At least 2 prior second-generation anti-androgen therapies approved for mCRPC and not have received docetaxel in mCRPC setting and eligible for docetaxel. | Open to accrual |

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| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Valerin | J. Balangue | UCI 20-67: A Phase I/II, First-In-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF1001 in Patients with Locally Advanced or Metastatic Solid TUmors, and Expansion in Selected Indications | DF1001: Immunotherapy targeting NK cells; Pembro: Anti-PD-1 | • Histologically or cytologically proven locally advanced or metastatic transitional cell carcinoma of the urothelium (including renal pelvis, ureters, urinary urothelial, urethra).<br>• Primary tumor must have documented HER2 expression by immunohistochemistry.<br>• ECOG status of 0 or 1 at study entry and life expectancy of at least 3 months.<br>• Have recieved 1 platinum-containing regimen for inoperable locally advanced or metastatic urothelial carcinoma with radiographic progression or recurrent disease.<br>• Must have received treatment with a checkpoint inhibitor with radiographic progression. | Open to accrual |
| Nagasaka | A. Serwanska | UCI 20-68: A Phase II Study of Seribantumab (FTN100) in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors | Seribantumab: ERBB inhibitor | • NRG1 gene fusion<br>• Advanced or metastatic (Stage IIIB or IV) or unresectable<br>• 2nd or 3rd line treatment (no previous ERBB/HER2/HER3 treatment for cohort 1) | Open to accrual |
| Rezazadeh | TBA | UCI 20-179: A Phase I/IB First-in-Human Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Patients with Advanced Solid Tumors | BBP-398: SHP2 inhibitor | <u>Dose Escalation Phase:</u><br>• Diagnosis of advanced (primary or recurrent) or metastatic solid tumor with MAPK-pathway alterations (excluding BRAF V600X).<br><u>Dose Expansion Phase:</u><br>• Advanced or metastatic KRAS G12C of NSCLC or non-NSCLC with no available standard of care or curative therapies<br>• Advanced or metastatic solid tumor with other MAPK-pathway alterations (excl. BRAF V600X) with no available standard of care or curative therapies. | Pending activation |
| Ou | K. Gomez | UCI 20-211: A Phase I, Open-Label, Multi-Center, Dose Escalation and Dose Expansion Study to Evaluate the Safety Tolerability, Pharmacokinetics, and Preliminary Evidence of Anti-Tumor Activity of PF-07284892 (Arry-558) as a Single Agent and in Combination Therapy in Participants with Advanced Solid Tumors | PF-07284892: SHP-2 inhibitor | • Histological or cytological diagnosis of ALK-positive advanced NSCLC, colorectal carcinoma with BRAF V600 E mutation, or RAS-mutant, NF1-mutant or BRAF class 3-mutant solid tumor. | Suspended |
| Dayyani | J. Balangue | UCI 20-213: Phase I First-in-Human (FIH) Study of Leukocyte Immunoglobulin-Like Receptor B2 (LILRB2) Inhibitor Monoclonal Antibody (mAb) JTX-8064, as Monotherapy and in Combination with a Programmed Cell Death Receptor-1 (PD-1) Inhibitor, in Adult Subjects with Advanced Refractory Solid Tumor Malignancies | JTX-8064: LILRB2 inhibitor | • Histologically or cytologically confirmed advanced/metastatic extracranial solid tumor:<br>- Stages 1 and 2: Histologically or cytologically confirmed advanced/metastatic extracranial solid tumor.<br>- Cohort 4A: 2L/3L clear cell renal cell carcinoma. Subjects just have progressed on or after prior PD-(L)1 therapy.<br>- Cohort 4B: 2L to 4L, PD-(L)1 naive soft tissue sarcoma.<br>• Must not have had prior JTX-8064, LILRB2, or ILT4-directed therapy. | Open to accrual |
| Harris | TBA | UCI 21-03: A Single-Arm Pilot Study of Pembrolizumab Combined with Stereotactic Ablative Radiotherapy for Patients with Advanced or Metastatic Sarcoma | | | Pending activation |
| Dayyani | J. Balangue | UCI 21-10: A Phase I Dose-Escalation and Dose Expansion Study of TJ033721 in Subjects with Advanced or Metastatic Solid Tumors | TJ033721: anti CLDN18.2 and anti 4-1BB | • Histologically confirmed advanced or metastatic solid tumor whose disease has progressed despite standard therapy who have no available standard treatment options.<br>• No prior exposure to CLDN18.2 - targeted therapy or 4-1BBagonists. | Open to accrual |
| Dayyani | B. Huynh | UCI 21-11: A Phase IB/II, Multicenter, Open-Label Study of TT-00420 Tablet, as Monotherapy or in Combination Regiments, in Patients with Advanced Solid Tumors | TT-00420: Aurora A/B and Janus kinase inhibitor | • Histopathological or cytologically confirmed locally advanced or metastatic solid tumors who have no available standard therapeutic treatment options.<br>• No hematologic malignancy, including leukemia (any form), lymphoma, and multiple myeloma.<br>• No history of primary central nervous system tumors or carcinomatous meningitis. | Pending activation |

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| **PI** | **CRC** | **Protocol #/Title** | **Mechanism** | **Primary In/Ex Criteria** | **Status** |
| Ou | O. Quines | UCI 21-12: A Phase I/IB, Open-Label, Multicenter, Dose-Escalation Study of RMC-5552 Monotherapy in Adult Subjects with Relapsed/Refractory Solid Tumors | RMC-5552: mTORC1 inhibitor | Dose-Escalation Phase:<br>• Participants with relapsed or refractory solid tumors who have failed, or are intolerant to, or are considered ineligible for standard-of-care therapies.<br>Dose-Expansion Phase:<br>• Participants with relapsed or refractory solid tumors harboring certain specific mutations/rearrangements that result in hyperactivation of the mTOR pathway (e.g. PIK3CA, PTEN, TSC1/2, STK11, MTOR, MYC, MAPK - please contact CRC for specific aberrations). | Open to accrual (Cohort 4c closed ) |
| Nagasaka | O. Quines | UCI-21-13: Phase I/II Study of BT5528 in Patients with Advanced Malignancies Associated with EphA2 Expression | BT5528: bicycle toxin conjugate targeting EphA2 | | Pending activation |
| Ou | C. Carrillo | UCI 21-38: An Open Label, First in Human (FIH), Phase I Trial of LVGN6051 as Single Agent and in Combination with Keytruda (Pembrolizumab) in Advanced or Metastatic Malignancy | LVGN6151: CD137 antagonist; Pembro: PD-1 antibody | • Histologically or cytologically confirmed advanced metastatis or unresectable malignancy, forewhich they have received all standard therapy or have been unable to tolerate standard therapy. | Open to accrual |
| Valerin | P. Keshtmand | UCI 21-40: A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications | DF6002: monovalent IL12-Fc; Nivolumab: Anti-PD-1 mAB | Dose Escalation Phase 1 and Phase 1b:<br>• Histologically or cytologically proven locally advanced or metastatic solid tumors, forwhich no standard therapy exists or standard therapy has failed among the following tumor types: meanoma, NSCLC, small cell lung, head and neck squamous cell, urothelial, gastric, esophageal, cervical, hepatocellular, Merkel cell, cutaneous squamous cell carcinoma, renal cell, endometrial, TNBC, ovarian, and prostate. | Open to accrual |
| Ou | K. Buttigieg | UCI 21-47: A Phase I/II Study of the Highly Selective ROS1 Inhibitor NUV-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1) | | • Histologically or cytologically confirmed metastatic solid tumors with documented ROS1 rearrangement.<br>• No primary driver alteration other than ROS1. For example, NSCLC with a targetable mutation in EGFR, ALK, MET, RET, or BRAF. | Open to accrual |
| Ou | J. Choe | UCI 21-53: A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors | LY3537982: KRAS-G12C inhibitor | * Must have KRASG12C mutation in tumor tissue or circulating tumor DNA<br>* Proven diagnosis of locally advanced, unresectable, and/or metastatic cancer<br>* No active fungal, bacterial, or viral disease<br>* No resrious cardiac conditions<br>* No prior treatment with any KRAS G12C small molecule inhibitor, except in P1A dose esc. cohort and cohort E1. | Open to accrual |
| Nagasaka | TBA | UCI 21-62: Phase I/II Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Anti-TIM-3 Monoclonal Antibody BGB-A425 in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab in Patients with Advanced Solid Tumors | BGC-A425: anti-TIM-3: Tislelizumab: anti-PD-1 | | Pending activation |
| Fortier | TBA | UCI 21-127: Goal Directed Intervention for Adolescent and Young Adult Cancer Survivors | Interview | • Age 15-21 at the time of consent.<br>• Completion of primary medical treatment for cancer within 1 year at the time of consent. | Pending activation |
| Dayyani | S. Khosravi | UCI 21-146: An Open-Label, Multi-Center, Phase I/II Dose Escalation and Expansion Study to Assess the Safety, Tolerability, Anti-Tumor Activity and Pharmacokinetics of MRG004A in Patients with Tissue Factor Positive Advanced or Metastatic Solid Tumors | MRG004A: antibody-drug conjugate | | Pending activation |
| Cho | TBA | UCI 21-153: A Phase I, Open-Label, Dose Escalation and Expansion Study Evaluating the Safety and Pharmacodynamics of PF-07263689, Either Alone or in Combination with an Anti-PD-1 Antibody, in Previously Treated Participants with Selected Locally Advanced or Metastatic Solid Tumor | | | Pending activation |
| Zell | TBA | UCI 21-174: Preserving Medical Records after a Cancer Diagnosis for Subsequent Generations to Use | | | Pending activation |
| BASKET TRIALS | | | | | |

UCI Chao Family Comprehensive Cancer Center

# Genitourinary

| PI | CRC | Protocol #/Title | Mechanism | Primary In/Ex Criteria | Status |
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| Tewari | TBA | UCI 21-189: A Multicenter, Open-label, Phase 2 Basket Study of MK-7684A, a Coformation of Vibostolimab (MK-7684) with Pembrolizumab (MK-3475), With or Without Other Anticancer Therapies in Participants with Selected Solid Tumors | | | Pending activation |
| Chow | TBA | UCI 21-208: An Open-Label, Multicenter, Phase I Study of IGM-8444 as a Single Agent and in Combination in Subjects with Relapsed and/or Refractory Solid Cancers | IGM-8444: agonistic IgM antibody | | Pending activation |
| Bota | M. Tharani | SWOG S1609 DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors<br>18: Squamous cell carcinoma variants of the genitourinary (GU) system<br>19: Spindle cell carcinoma of kidney, pelvis, ureter<br>50: PD-L1 amplified tumors (NEW)<br>53: Treatment-emergent small-cell neuroendocrine prostate cancer (t-SCNC) | Ipilimumab: Anti-CTLA-4 mAb; Nivolumab: Anti-PD-1 mAb | • Histologically confirmed rare cancer identified in §18.1, NOS rare tumors, or tumor of unknown primary cohorts.<br>• PD following ≥1 line of standard therapy and there must not be other approved/standard therapy available that has been shown to prolong OS. Includes patients who cannot receive standard therapy due to medical issues.<br>• ≥4 Week washout of prior anti-CTLA-4 or anti-PD-1/anti-PD-L1 therapy prior to registration. | Open to accrual |
| Bota | D. Na | ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH) | Varies per mutation | • Positive for specific mutations. | Open to accrual |
| Kong | M. Tharani | ETCTN-10129: A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 Mutant Advanced Solid Tumors | PARP Inhibitor | • Diagnosed with solid malignant tumor that has progressed despite standard therapy, or for which no effective standard therapy exists.<br>• Biopsy confirmation of an IDH1 or IDH2 mutation associated with neomorphic activity of the encoded proteins.<br>• No prior treatment with any PARP inhibitor, including olaparib.<br>• No other melignancy within the last 5 years except: treated non-melanoma skin cancer, treated in situ cancer or the vervix, ductal carinoma in situ, stage 1, grade 1 endometrial carcinoma, or other solid tumors including lymphomas (without bone marrow involvement). | Open to accrual |

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