Genitourinary

TESTICULAR CANCER: Observational					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Rezazadeh	TBD	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. • 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. • No lifetime history of psychiatric of cognitive disturbance as per self-report or medical record. • No self-reported medical conditions that affect the immune system and would confound immune evaluation. • Not a regular smoker (daily use).	Pending activation
PROSTATE CANCER: Surgical Candidates					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Uchio	N. De La Rosa	UCI-21-136: Pivotal Study of the NanoKnife System for Ablation of Prostate Tissue in an Intermediate-Risk Patient Population	Irreversible Electroporation (IRE)	Inc: * Has Gleason score 3+4 or 4+3 *no evidence of extraprostatic extension by mpMRI * no evidence of seminal vesicle invasion by mpMRI, and if suspected, confirmed by biopsy * Physician is able to visualize prostate gland adequately on transrectal ultrasound imaging during qualifying biopsy * Has a transperineal or transrectal targeted prostate biopsy of lesion, plus 10-14 core systematic biopsy to include adequate sampling of the peripheral zone correlating with an intermediate risk lesion3 in the area of the MR-visible lesion * A visible lesion on mpMRI that is accessible to Irreversible Electroporation (IRE) treatment Ex: * Has known hypersensitivity to pancuronium bromide, atricurium or cisatricurium * Is unfit for anesthesia or has a contraindication for agents listed for paralysis * Has had prior major rectal surgery (except hemorrhoids) * Is unfit for pelvic MRI scanning * Is a member of a vulnerable population, such as cognitively impaired or incarcerated, that could expose them to undue influence, coercion, or inability to obtain informed consent	Open to accrual
PROSTATE CANCER: Hormone-Sensitive					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Rezazadeh	A. Macaraeg	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	Inclusion: - Have at least one bone met, soft tissue, visceral lesion w/in 28 days prior to randomization -minimally treated with up to 45 days of LHRH, dicon prior to study therapy or 45 days after start of LHRH. Up to 45 days of CYP17 inhibitor or ARDT exposure. No CYP17 inhibitor or ARDT exposure for earlier stages of pristate cancer. Exclusion: - Require urgent exposure to taxane-based chemo - prior systemic anti-prostate cancer therapy, chemotherapy, Polypolymerase (PARP) inhibitors, immunotherapy or biological therapy - Previous treatment within 6 months of randomization: Strontium-89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223, hemi-body irradiation. No previous PSMA-targeted radioligand therapy - Symptomatic cord compression - Any condition that precludes raised arms position	Open to accrual

PROSTATE CANCER: Hormone-Sensitive					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Uchio	TBD	UCI 22-52: A Phase II Open-Label Extension Study for Subjects with Prostate Cancer who Previously Participated in an Enzalutamide Clinical Study			Pending activation
Seyedin	A. Macaraeg	NRG-GU009: Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk And Intensification of Concurrent Therapy for Higher Genomic Risk With Radiation (Predict-Rt*)		• Pathologically confirmed adenocarcinoma of prostate within 180 days prior to registration. • High-risk disease defined as having at least one of the following: PSA > 20 ng/mL prior to starting ADT, cT3a-T4 by digital exam, gleason score of 8-10, or node positive by conventional imaging with a short axis of at least 1.0 cm. • No metastatic disease outside of the pelvic nodes. • No prior systemic chemotherapy within 3 years prior to registration for the cancer on study. • No prior prostatectomy. • No prior radiotherapy to the re3gion of the study cancer that would result in overlap of radiation therapy fields.	Open to accrual
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. • Progression within 6 months prior to screening. • Ongoing androgen deprivation. • No prior radium/radiopharmaceutical treatment. **COHORTS F, H, I:** Inc: - Have t-NE or de novo metastatic prostate cancer defined by ≥1% neuroendocrine cells located in discrete regions of a recent biopsy specimen from a metastasis - A core or excisional biopsy from soft tissue or a bone biopsy is required.	Cohorts F, H, I, and Retreat 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	Histologically confirmed adenocarcinoma of the prostate and metastatic castrate resistant with tumor progression while on androgen deprivation therapy (ADT; including orchiectomy) with castrate levels of serum (total) testosterone (≤1.7 nmol/L or 50 ng/dL) defined by PSA and/or radiographic criteria according to PCWG3. Castrate levels of testosterone must be maintained by surgical or medical means throughout study conduct.	Open to accrual
Rezazadeh	M. Popal	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	Part B - Phase 2 Cohort Expansion • Testosterone <50 ng/dL • 1-2 prior second generation anti-androgen agents for CRPC. • Subgroup 1: Tumors harboring AR T878 and/or H875 mutations. -At most 1 chemotherapy regimen in CSPC and CRPC settings. • Subgroup 4: Less pre-treated group. -Received only 1 prior AR second generation therapy either as treatment for CSPC or CRPC and no more than 1 regimen in CRPC setting. -No prior chemotherapy. • Results of tumor DNA sequence analysis, including AR gene, known prior to initiation of treatment within 3 months of enrollment.	Suspended
Mar	S. Boggs	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 • 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. • Progression after abiraterone, enzalutamide, docetaxel, or other secondary hormonal therapy. There is no maximum number of prior therapies. • No prior therapy with radionuclides, hemibody external radiation, or systemic radiotherapy with radioisotopes. • Able to discontinue medications that are potent inhibitors, inducers or sensitive substrates of CYP3A4/5 or CYP2C19. • Able to discontinue concomitant H2 blockers or PPIs.	Open to accrual

PROSTATE CANCER: Non-Treatment					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Ahlering	J. Tran	UCI 98-41 Outcomes and Assessment of Prostate Cancer at UCIMC	Radical Prostatectomy		Open to accrual
Ahlering	J. Tran	UCI 17-07: Patient Reported Outcomes via Online Questionnaire (PROVOQ): Post-Radical Prostatectomy Outcome Assessment	Online questionnaire		Open to accrual
Uchio	TBD	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 * Diagnosis of prostate cancer, clinical stage T1 or T2, with no evidence of metastasis * PSA less than 50 ng/mL *Not previously undergone any treatment for prostate cancer *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	TBD	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
PROSTATE CANCER: Non-Treatment					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Dayyani	M. Nguyen	UCI 22-109: A Randomized, Double-blind, Double-dummy, Parallel Group Study to Assess the Efficacy and Safety of Palonosetron HCl Buccal Film versus IV Palonosetron 0.25 mg for the Prevention of Chemotherapy-induced Nausea and Vomiting in Cancer Patients Receiving Moderately Emetogenic Chemotherapy	Palonosetron HCl Buccal Film 0.50 mg to IV palonosetron 0.25 mg	Inc: * Chemotherapy naïve w/ confirmed malignant disease or non-naïve with proven diagnosis of cancer * Karnofsky index ≥ 50 * If a subject experienced no more than mild nausea following any previous chemotherapy regimen, he/she can be enrolled at the discretion of the investigator Ex: * Received any investigational drug 30 days prior to study entry * Received any drug or were scheduled to receive any drug with anti-emetic efficacy within 24 hours of the start of treatment through Day 5of the study * Enrollment in a previous study with palonosetron * Seizure disorder requiring anticonvulsant medication unless clinically stable * Experienced any vomiting, retching, or NCI Common Toxicity Criteria grade 2 or 3 nausea in the 24 hours preceding chemotherapy * Ongoing vomiting from any organic etiology	Pending activation
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. • 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. • No more than 2 prior systemic regimens for locally advanced/metastatic RCC.	Open to accrual

RENAL CANCER: Adjuvant					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Rezazadeh	R. Rizkallah	UCI 21-228: A Multi-Center, Double-Blind, Randomized Phase III Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy (6482-022)	Belzutifan: HIF-2α antagonist; Pembrolizumab: anti-PD-1	Inc: * Confirmed high risk of M1 NED RCC * Complete resection of the primary tumor and solid, isolated, soft tissue mets in M1 NED RCC pts * Undergone nephrectomy a/o metastectomy <= to 12 weeks prior * Tumor free before randomization confirmed via BICR by CT or MRI * Provide nephrectomy tissue Exc: * Residual thrombus post nephrectomy in vena renalis or vena cava * Clinically significant CVD within 6 months of 1st dose of study intervention * Pre-exisitng brain or bone mets * Recieved colony-stimulating factors or recombinant EPO or transfusion 28 days prior to study intervention	Suspended
Mar	R. Rizkallah	UCI 21-230: A Phase III, Randomized, Controlled, Multicenter, Open-Label Study to Compare Tivozanib in Combination with Nivolumab to Tivozanib Monotherapy in Subjects with Renal Cell Carcinoma Who Have Progressed Following One or Two Lines of Therapy Where One Line has an Immune Checkpoint Inhibitor		Inc: * Radiographic disease progression during or following at least 6 weeks of treatment with ICI for locally advanced or metastatic RCC with a clear cell component either in first- or second-line treatment * Subjects must have progressed no longer than 6 months prior to randomization * Subjects must have recovered from the AEs of prior therapy or returned to baseline Ex: * More than 2 prior lines of therapy in the advanced or metastatic setting * History of life-threatening toxicity related to prior immune therapy * Condition requiring systemic treatment with either corticosteroids (> 10 mg daily prednisone equivalent) within 14 days of treatment initiation or other immunosuppressive medications within 30 days of randomization * Prior treatment with tivozanib.	Open to accrual
RENAL CANCER: Non-Treatment					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Landman	R. Yoon	UCI 13-03: Office-Based Percutaneous Ultrasound-Guided Renal Biopsy	Prospective database	• No coagulopathy or other bleeding disorder. • No active urinary tract infections. • 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			Suspended
Uchio	D. Hassan	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. • Failed one prior course of BCG. • Confirmed diagnosis of high risk non-muscle-invasive (T1, High Grade Ta and/or CIS) bladder TCC. • No muscle invasive (T2-T4), locally advanced non-resectable, or metastatic urothelial carcinoma. • ≥9 Doses of BCG within the last 9 months.	Open to accrual
Uchio	TBD	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. • Have all Ta and/T1 disease resected and all CIS resected or fulgurated. • Ineligible for radical cystectomy or refused radical cystectomy.	Open to accrual

UROTHELIAL CANCER: Non-Muscle Invasive					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Uchio	TBD	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. • 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. • No current high-grade, or muscle invasive urothelial carcinoma of the bladder. • No current or previous CIS in the upper urinary tract. • No history of invasive T2 urothelial cancer in the past 2 years. • No BCG or local chemotherapy in the upper urinary tract within 2 months of enrollment. • No systemic chemotherapy within 2 months of enrollment.	Pending activation
Uchio	D. Hassan	UCI 21-41: A Study of Intravesical Enfortumab Vedotin for Treatment of Patients with Non-Muscle Invasive Bladder Cancer	Intravesical Enfortumab Vedotin	Subjects must have histologically confirmed, non-muscle invasive urothelial (transitional cell) carcinoma with CIS (with or without papillary disease). Histological confirmation should occur within 60 days prior to first dose of study treatment.	Open to Accrual
Uchio	P. Duffy	UCI 22-69: A Phase I/II Study of EG-70 as an Intravesical Administration to Patients with BCG-Unresponsive NMIBC and High-Risk NMIBC Patients Who Are BCG Naïve or Received Incomplete BCG Treatment	EG-70	Inc: * BCG-Unresponsive Patients: persistent high-grade disease after receiving intravesical BCG induction, T1 high-grade disease residual at the first evaluation following induction BCG * BCG-Naïve or BCG-Incompletely Treated Patients (Phase 2 Only): persistent or recurrent high-grade disease after incomplete BCG (at least 1 dose) treatment and/or who have not yet received any treatment with BCG due to unavailability, but who have previously been treated with at least 1 dose of intravesical chemotherapy following transurethral resection of bladder tumor	Pending activation
UROTHELIAL CANCER: Muscle Invastive					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Rezazadeh	R. Rizkallah	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). • Medically fit for cystectomy and able to receive neoadjuvant therapy.	Open to accrual
Uchio	TBD	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. • Ineligible for or elected to not undergo radical cystectomy. • No other active malignancies. • 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. • No intervening intravesical chemotherapy or immunotherapy from the time of most recent TURBT to starting study treatment. • 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**
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). • 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 MIBC including neoadjuvant chemotherapy for current tumor.	Open to accrual - only at Orange
Rezazadeh	S. Boggs	UCI 22-128: A Phase I/II Open-Label Rolling-Arm Umbrella Platform Study of Investigational Agents With or Without Pembrolizumab in Participants with PD-1/L1 Refractory Locally Advanced or Metastatic Urothelial Carcinoma (KEYMAKER-U04): Substudy 04A	Pembrolizumab	In: * Has PD-1/L1 refractory locally advanced or mUC * Has resolution of toxic effect(s) of the most recent prior therapy to Grade 1 or less (except alopecia) Ex: * Has had prior treatment with an anti-ROR1 therapy * Neuropathy grade >1	Suspended
Mar	M. Popal	UCI 22-39: A Phase II Multi-Cohort, Open-Label, Multi-Center Clinical Study Evaluating the Efficacy and Safety of Disitamab Vedotin (RC48-ADC) in Subjects with HER2-Expressing Locally-Advanced Unresectable or Metastatic Urothelial Carcinoma	Disitamab Vedotin (RC48-ADC)	Inc: * LA/mUC with histopathological confirmation, including UC originating from the renal pelvis, ureters, bladder, or urethra. Mixed-cell type tumors are eligible as long as urothelial cell carcinoma is the predominant cell type * Subject must have received 1 or 2 lines of prior systemic therapy for LA/mUC, including 1 line of platinum-containing chemotherapy * HER2-expressing status determined by the central laboratory to be IHC 1+, 2+ or 3+ Ex: * Known hypersensitivity to disitamab vedotin or any of its components * Toxicity from a previous treatment has not returned to Grade 0-1 * Prior MMAE-based ADCs (eg, enfortumab vedotin) or HER2-directed therapy	Open to accrual
Mar	R. Rizkallah	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. • PD-L1 status determined centrally by HistogeneX. • May have up to two prior lines of chemotherapy for advanced disease. • No prior treatment with anti-PD-1, or anti-PD-L1 therapeutic antibody or pathway targeting agents or eribulin.	Suspended
Rezazadeh	M. Popal	ETCTN-10144: A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and Other Genitourinary Tumors with DNA-Repair Defects	PARP Inhibitor	• Histologically confirmed diagnosis of non-prostate GU cancer • Histologically confirmed urothelial carcinoma of the urothelial tract/bladder cancer. • 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. • No prior treatment with olaparib or any other PARP inhibitor. • No myelodysplastic syndrome/acute myeloid leukemia. Cohort 1: • Have confirmed presence of high TMB or one or more of the following genes: BRCA1, BRCA2, ATM, BAP1, MSH2, PALB2, and BRIP1 Cohort 2: • 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. Cohort 3: • 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
Nagasaka	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. • 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
Valerin	M. Nguyen	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). • Primary tumor must have documented HER2 expression by immunohistochemistry. • ECOG status of 0 or 1 at study entry and life expectancy of at least 3 months. • Have recieved 1 platinum-containing regimen for inoperable locally advanced or metastatic urothelial carcinoma with radiographic progression or recurrent disease. • Must have received treatment with a checkpoint inhibitor with radiographic progression.	Open to accrual
Rezazadeh	M. Popal	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	Dose Expansion Phase: • Advanced or metastatic solid tumor with other MAPK-pathway alterations (excl. BRAF V600X) with no available standard of care or curative therapies. • Cohort A: Advanced or metastatic KRAS G12C of NSCLC with no available standard of care or curative therapies. • Cohort B: Advanced or metastatic KRAS G12C of non-NSCLC with no available standard of care or curative therapies. • Cohort A: Advanced or metastatic NF1 LOF solid tumor with no available standard of care or curative therapies. • Cohort D: Advanced of metastatic EGFR-mutant NSCLC that progressed on standard of care EGFR TKI therapies, with no available standard of care or curative therapies.	Open to accrual
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. • No prior exposure to CLDN18.2 - targeted therapy or 4-1BBagonists.	Open to accrual
Ou	R. Chang	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: • Participants with relapsed or refractory solid tumors who have failed, or are intolerant to, or are considered ineligible for standard-of-care therapies. Dose-Expansion Phase: • 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)

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Nagasaka	R. Chang	UCI-21-13: Phase I/II Study of BT5528 in Patients with Advanced Malignancies Associated with EphA2 Expression	BT5528: bicycle toxin conjugate targeting EphA2	Part A • Histologically confirmed metastatic recurrent melignany solid tumor who must have exhausted all appropriate treatment options per local guidelines and must have failed at least one prior line of therapy with evidence of radiographic progression on the most recent line. • Cohort A1-4 for Part A-1 monotherapy or Cohort A2-3 for Part A-2 combination therapy must have tumor tissue with confirmation of positive EphA2 tumor expression. • Patients with ovarian or urothelial cancer in Cohort 1-4 for Part A-1 monotherapy or Cohort A2-3 for Part A-2 conbination therapy must have tumor tissue available but may be enrolled without prior confirmation of EphA2 tumor expression. Part B • Histologically confirmed metastatic recurrent disease that is non-small cell lung cancer, ovarian cancer, triple-negative breast cancer, gastric/upper gastrointestinalcancer, head and neck cancer, or urothelial cancer. • Must have failed or are ineligible for all appropriate treatment options per local guidelines and have evidenace of radiographic progression on the most recent line of therapy.	Open to accrual
Chow	E. Torrison	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	B. Huynh	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	<u>Dose Escalation Phase 1 and Phase 1b:</u> • 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. • No primary driver alteration other than ROS1. For example, NSCLC with a targetable mutation in EGFR, ALK, MET, RET, or BRAF.	Open to accrual
Nagasaka	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 * Proven diagnosis of locally advanced, unresectable, and/or metastatic cancer * No active fungal, bacterial, or viral disease * No resrious cardiac conditions * No prior treatment with any KRAS G12C small molecule inhibitor, except in P1A dose esc. cohort and cohort E1.	Open to accrual

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Nagasaka	J. Choe	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	Inclusion: - Patient has not received prior therapy targeting TIM-3 - must meet the Child-Pugh A classification for liver function w/in 7 days before first dose - ECOG ≤ 1 Exclusion - Active untreated brain mets - history of interstitial lung disease - undergone any major surgical procedure within 28 days before 1st treatment - hypersensitivity to monoclonal antibodies - received any herbal medicine or Chinese patent medicines used to control cancer within 14 days of 1st dose - Was administered a live vaccine ≤ 28 days prior to study - Underlying medical conditions or alcohol or drug abuse or dependence	Open to accrual
Fortier	TBD	UCI 21-127: Goal Directed Intervention for Adolescent and Young Adult Cancer Survivors	Interview	• Age 15-21 at the time of consent. • Completion of primary medical treatment for cancer within 1 year at the time of consent.	Pending activation
Dayyani	M. Duron	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	Part B • Documented Tissue Factor in tumor biopsy by immunohistorychemisty. • Histologically or cytologically confirmed unresectable or metastatic cancer with disease progression during prior therapy, or relapse or progression following approved standard therapy for their tumor types.	Open to accrual
Nagasaka	C. Ramirez	UCI 21-161: A Phase I/II Dose Escalation and Dose Expansion Study of BA3021 Alone and in Combination with Nivolumab in Patients with Advanced Solid Tumors	BA3021: antibody drug conjugate; Nivolumab: PD-1 checkpoint inhibitor	Inc: * Minimum of 1 measurable tumor via RECIST * Tissue for ROR2 and other gene expression testing * Full SARS-Co V-2 vaccination * Completed prior treatment w/ radio, chemo, or targeted small molecule therapy 2 weeks prior to study * Competed any nitrogen mustard agents, melphalan, or carmustine 6 weeks prior to 1st dose * Recieved any prior autologous hematopoietic stem cell infusion at least 8 weeks prior to 1st study dose Exc: * Clinically significant CVD * Known non-controlled mets * Severe renal impairment	Open to accrual
Zell	TBD	UCI 21-174: Preserving Medical Records after a Cancer Diagnosis for Subsequent Generations to Use	Medical Record Collection		Pending activation

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	K. Gomez	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	MK-7684: anti-TIGIT; MK-3475: anti PL-1	• No prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-TIGIT agent. • Cohort A: Histologically or cytologically confirmed advanced squamous cell carcinoma, adeonosquamous carcinoma, or adeonocarcinoma of the cervix which has progressed on satandard of care chemotherapy. • Cohort B: Histologically or cytologically confirmed advanced endometrial cancer that has progressed after 1 prior systemic platinum-based chemotherapy. May have had up to 2 lines of platinum-based chemotherapy if 1 was in the neoadjuvant or adjuvant treatment setting. • Cohort C: Histologically or cytologically confirmed advanced HNSCC that is considered incurable by local therapies and whose tumor express PD-L1 (CPS≥1). • Cohort D: Histologically or cytologically confirmed advanced unresectable biliary adenocarcinoma that has progressed after 1 prior systemic therapy. No mixed HCC/cholangiocarcinoma or Ampulla of Vater cancers. • Cohort E: Histologically or cytologically confirmed advanced adeonocarcinoma or squamous cell carcinoma of the esophagus or advanced/metastatic Siewert type I adenocarcinoma of the GEJ that is unresectable and not previously treated with systemic therapy. • Cohort F: Histologically or cytologically confirmed local TNBC that is locally unresectable but not previously treated with chemotherapy and cannot be treated with curative intent or metastatic that has not been previously treated with chemotherapy. • Cohort G: Histologically, radiologically, or cytologically confirmed HCC excluding fibrolamellar, sarcomatoid, or mixed cholangio-HCC tumors that has not been previously treated with systemic therapy.	Open to accrual
Chow	M. Nguyen	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	In: * Patients who are either refractory to or intolerant of existing standard therapy or for whom no effective further standard of care therapy exists * No more than three prior therapeutic regimens Ex: * Prior DR5 agonist therapy * Prior Bcl-family inhibitor therapy * Concomitant use of agents well known to cause liver toxicity * Current treatment with medications that are well known to prolong the QT interval * History of severe allergic or anaphylactic reactions to antibody therapy * Palliative radiation to bone metastases within 2 weeks prior to Day 1 * Major surgical procedure within 4 weeks prior to Day 1	Open to accrual

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Chow	B. Huynh	UCI 21-229: Phase I, Open-Label Study to Evaluate Safety, Tolerability and Preliminary Efficacy of Modified Salmonella Typhimurium SGN1 in Patients with Advanced Solid Tumor	SGN1: therapeutic bacterium	In: - Finished anti-tumor therapy ≥ 4 weeks prior to the first dose of study drug - atleast 1 measurable lesion per RECIST Ex: - steroid or steroid hormone > 10 mg/day within 14 days prior to first infusion - Currently using antibiotic - Tumors in hollow organs - Patients with implants such as pacemakers, prosthetic cardiac valves or metal orthopedic prostheses	Open to accrual
Moyers	B. Huynh	UCI 21-247: A First-in-Human, Multicenter, Open-Label, Phase I Dose-Escalation and Cohort Expansion Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAB004 as Monotherapy and in Combination with Toripalimab in Subjects with Advanced Solid Malignancies Including Lymphoma	TAB004: anti-MUC1 antibody; Toripalimab: anti PD-1	Inc: * Patients with histologically or cytologically confirmed locally advanced unresectable or metastatic solid tumors or lymphoma that have progressed following prior treatment * Measurable disease per RECISTv1.1 Ex: * Any concurrent anti-cancer therapy, such as but not limited to chemotherapy, targeted therapy, radiotherapy, immunotherapy, or biologic therapy. Radiation treatment or surgery for palliative intent is allowed provided that lesions other than those receiving radiation are available to measure response * Prior exposure to anti-BTLA or anti-HVEM antibodies for patients enrolled into Part A or B	Open to accrual
Mar	M. Popal	UCI 22-17: An Open-Label, Escalating Multiple-Dose Study to Evaluate the Safety, Toxicity, Pharmacokinetics, and Preliminary Activity of BTX-1188 in Subjects with Advanced Malignancies	BTX-1188: GSPT1 and IKZF1/3 protein degrader	In: - Relapsed or refracotry AML, B cell NHL, Histologically or cytologically documented, incurable or metastatic solid tumor that has failed all available standard therapies with known benefit Ex: - Diagnosis of acute promyelocytic leukemia - Immediate life-threatening severe complications of leukemia such as uncontrolled bleeding, pneumonia with hypoxia or shock, and/or disseminated intravascular coagulation	Suspended
Dayyani	N. Ferrand	UCI 22-26: Open-Label, Multicenter, Phase I Study to Evaluate the Maximum Tolerated Dose of Orally Administered CB-03-10 with Dose Expansion Phase, in Subjects with Advanced Solid Tumors	Androgen and glucocorticoid receptor antagonist	• Part 1 (Dose Escalation): histologically or cytologically confirmed relapsed or refractory advanced or metastatic solid tumor of any origin, not amenable to standard of care therapy • Measurable or evaluable disease per RECIST v1.1 criteria • Exclusion: Known brain metastases, spinal cord compression, carcinomatous meningitis or leptomeningeal disease unless appropriately treated and neurologically stable for > 4 weeks	Open to accrual
Dayyani	TBA	UCI 22-37: A Phase Ia/Ib Open-Label Study to Assess the Safety, Pharmacokinetics, and Antitumor Activity of Oral TACH101 in Patients with Advanced or Metastatic Solid Tumors	Active IP	Inc: * Ph 1a: Patient must have advanced or metastatic solid tumor that has progressed or was non-responsive or intolerant to available therapies and for which no standard or available curative therapy exists, or, in the opinion of the investigator, is not a candidate for * Ph 1b: Patient must have advanced or metastatic gastrointestinal tumors or MSI-H CRC that has progressed or was non-responsive or intolerant to standard therapy or unlikely to tolerate or unable to derive significant clinical benefit from appropriate standard of care therapy. * Presence of advanced or metastatic disease that is measurable according RECIST Ex: * Patients who have received allogenic hematologic stem cell transplant * Major surgery within 2 months prior to screening * Prior gastrectomy or upper bowel removal or any other gastrointestinal disorder that would interfere with the absorption, or excretion of TACH101	Pending activation

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	K. Gomez	UCI 22-42: Phase I/II, Open-label Dose Escalation and Dose Expansion Study of TransCon TLR7/8 Agonist, Alone or in Combination with Pembrolizumab in Participants with Locally Advanced or Metastatic Solid Tumor Malignancies	TransCon TLR7/8 Agonist, Alone or in Combination with Pembrolizumab	Inc: * Participants must have histologically confirmed locally advanced, recurrent or metastatic solid tumor malignancies that cannot be treated with curative intent * Patients in neoadjuvant cohorts are exempt * Participants must have progressed on or be intolerant of available SOC treatment options or have disease for which there is no SOC treatment available * At least 2 lesions of measurable disease per RECIST 1.1 * Willingness to undergo pre-treatment and on-treatment biopsies as required for each Part of the study Ex: * Participants who have been previously treated with a TLR agonist (excluding topical agents for unrelated disease) are not eligible * Other active malignancies within the last 2 years are excluded. * Active autoimmune diseases	Pending activation
Ou	K. Buttigieg	UCI 22-87: Phase I/IB Multicenter Open-Label Study of RMC-6236 in Subjects with Advanced Solid Tumors Harboring Specific Mutations in KRAS	RMC-6236	Inc: * Pathologically documented, locally advanced or metastatic malignancy with KRASG12A, KRASG12D, KRASG12R, KRASG12S, or KRASG12V mutations * received prior standard therapy appropriate for tumor type and stage Ex: * Subject with tumors harboring KRASG12C mutations are not eligible, unless otherwise specified for Dose Expansion * Subjects with primary central nervous system (CNS) brain tumors. * Subject has known or suspected leptomeningeal or brain metastases or spinal cord compression. * Subjects with seizure disorder requiring antiepileptics.	Pending activation
Ou	R. Chang	UCI 22-88: Phase I/IB, Multicenter, Open-Label, Dose Escalation and Dose Expansion Study of RMC-6291 Monotherapy in Subjects with Advanced KRASG12C Mutant Solid Tumors	RMC-6291 Monotherapy	Inc: * Subject must have pathologically documented, locally advanced or metastatic KRASG12C-mutated solid tumor malignancy previously treated with BOTH immunotherapy and chemotherapy Ex: * Subjects has primary central nervous system (CNS) tumors * Subject has known or suspected leptomeningeal or brain metastases or spinal cord compression * Subject has a prior history of interstitial lung disease * Known active severe acute respiratory syndrome coronavirus 2 * Subject has a history of cerebrovascular accident or transient ischemic attack within previous 6 months of signing the ICF * Pulmonary embolism that resolved within 28-days of C1D1 * Subjects previously treated with a KRASG12C(ON) inhibitor	Open to accrual
Mar	TBD	UCI 22-130: OPtimal Treatment by Invoking Biologic Clusters in Renal Cell Carcinoma (OPTIC RCC)	Invoking Biologic Clusters		Pending activation
Valerin	TBD	UCI 22-171: A Phase I/II, First-In-Human, Multi-Part, Open-Label Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of DF9001 as a Monotherapy and in Combination with Nivolumab in Patients With Advanced (Unresectable, Recurrent, or Metastatic) Solid Tumors, and Expansion in Selected Indications	DF9001	Inc: * Ph1 - Histologically or cytologically proven locally advanced or metastatic solid tumors of epithelial origin with documented EGFR expression on tumor tissue by IHC and must have progressed on standard of care therapy * Ph1 expanstion - Disease must be measurable with at least 1 unidimensional measurable lesion by RECIST	Pending activation

BASKET TRIALS					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Kong	M. Nacisvalencia	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. • Biopsy confirmation of an IDH1 or IDH2 mutation associated with neomorphic activity of the encoded proteins. • No prior treatment with any PARP inhibitor, including olaparib. • 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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