

Colorectal					
Neoadjuvant Colorectal					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Zell	Amber Luna	A022104: The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing The Efficacy Of Triplet Versus Doublet Chemotherapy To Achieve Clinical Complete Response In Patients With Locally Advanced Rectal Cancer	chemotherapy	<ul style="list-style-type: none"> <li>Stage II or III rectal adenocarcinoma</li> <li>Tumor ≤ 12cm from the anal verge</li> <li>No prior treatment</li> </ul>	Open to accrual
Dr. Zell	Amber Luna	UCI 20-09: Short Course Radiation and TASOX (TAS102 plus Oxaliplatin) Chemotherapy in Operable Rectal Cancer, a Phase II Trial	Radiation + neoadjuvant TASOX; surgery	<ul style="list-style-type: none"> <li>Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0</li> <li>Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy</li> </ul>	Open to accrual
Adjuvant Colorectal					
Dr. Zell	Amber Luna	S0820: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III (PACES)	Ornithine decarboxylase (ODC) inhibitor + COX I/II inhibitor	<ul style="list-style-type: none"> <li>Stage 0-III colon or rectal adenocarcinoma treated per SOC with resection alone or in combination with radiation or chemotherapy</li> <li>Registration within 180-456 (inclusive) days of primary resection</li> <li>NED (post-operative colonoscopy)</li> </ul>	Open to accrual
Dr. Zell	Luisa Mejia Aguilar	NRG-GI005: Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)	ctDNA-guided therapy	<ul style="list-style-type: none"> <li>Confirmed stage IIA adenocarcinoma of the colon (T3, N0, M0) with at least 12 lymph nodes examined at time of resection</li> <li>Appropriate for active surveillance (e.g. no planned adjuvant chemotherapy) at discretion of and as documented by treating oncologist</li> <li>Distal extent of tumor &gt; 12 cm from anal verge on pre-surgical endoscopy or determined by surgical exam/pre-op imaging</li> </ul>	Open to accrual
Dr. Dayyani	Krissy Ghio	UCI 20-43: Proof of Concept Study of ctDNA Guided Change in Treatment for Refractory Minimal Residual Disease in Colon Adenocarcinomas	ctDNA-guided change in adjuvant treatment	<ul style="list-style-type: none"> <li>Stage II, III, or IV colorectal cancer after curative resection and eligible for adjuvant doublet chemotherapy for at least 3 additional months</li> <li>Must be ctDNA+ (Signatera) after at least 3 months of periop chemotherapy</li> <li>Prior treatment with irinotecan or TAS-102 is excluded</li> </ul>	Open to accrual
Dr. Cho	Amber Luna	NRG-GI008: Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (Circulate-US)	ctDNA-guided change in adjuvant treatment	<ul style="list-style-type: none"> <li>Stage IIIA, or IIIB colon adenocarcinoma (T1-3, N1/Nc1) with R0 resection</li> <li>Stage II, or IIIC colon adenocarcinoma with R0 resection who obtained Signatera ctDNA+ve essay results post operatively. Eligible for enrollment to Cohort B</li> <li>Must have had an en bloc complete gross resection of tumor.</li> </ul>	Open to accrual

Locally Advanced and Metastatic Colorectal Cancer - Newly Diagnosed					
Dr. Cho	Krissy Ghio	ECOG-EA2201: A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma	anti-CTLA4 + anti-PD1 + radiation	<ul style="list-style-type: none"> <li>Histologically confirmed rectal adenocarcinoma with inferior margin <math>\leq 15</math> cm from anal verge, based on colonoscopy and/or flexible sigmoidoscopy; T3-4Nx or TxN+ disease based on MRI Pelvis and CT of Abd/Chest</li> <li>Must have MSI-H or dMMR status based on IHC or PCR</li> <li>Must be chemo- or immunotherapy-naïve for rectal cancer; no prior RT to pelvis</li> <li>HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 mo.s of registration are eligible</li> </ul>	Open to accrual
Dr. Cho	TBD	UCI 21-67: Phase I study of epacadostat (INCB024360) added to preoperative chemoradiation in patients with locally advanced rectal cancer	IDO1 inhibitor	<ul style="list-style-type: none"> <li>Plans to proceed with neoadjuvant short course radiation and chemotherapy</li> <li>No prior anti-cancer therapy for rectal cancer</li> </ul>	Pending activation
Dr. Lee	Amber Luna	UCI 22-07: A Phase Ib/II Placebo Controlled, Double Blinded Study on the Efficacy and Safety of BXQ-350 in Combination with mFOLFOX7 and Bevacizumab in Newly Diagnosed Metastatic Colorectal Carcinoma	SAPc-DOPS/placebo + mFOLFOX + bev	<ul style="list-style-type: none"> <li>Must have measurable disease</li> <li>Cannot have confirmed dMMR or MSI-H</li> <li>Cannot have Type 1 or 2 diabetes mellitus</li> </ul>	Open to accrual
Dr. Cho	Luisa Mejia Aguilar	UCI 22-10: A Phase II/III, Randomized, Open-Label Study of Maintenance GRT-C901/GRT-R902, A Neoantigen Vaccine, in Combination with Immune Checkpoint Blockade for Patients with Metastatic Colorectal Cancer	vaccine + anti-CTLA4 + anti-PDL1 $\pm$ 5-FU and anti-VEGF	<ul style="list-style-type: none"> <li>Metastatic CRC who are planned for, or have received no more than 1 cycle of, first line treatment in the metastatic setting with 5-FU, oxaplatin and bevacizumab</li> <li>Measurable and unresectable disease per RECIST v1.1</li> <li>Availability of tumor tissue from a biopsy &lt; 12 months</li> </ul>	Open to accrual

Metastatic Colorectal - Recurrent					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Abi-Jaoudeh	Miranda Duron	UCI 21-39: An Open Label Phase II Study for the Treatment of Liver Metastatic Colorectal Cancer and Non-Small Cell Lung Cancer with a Combination of TATE (Trans-Arterial Tirapazamine Embolization) and Pembrolizumab	anti-PD-1 + TATE	<ul style="list-style-type: none"> <li>Histologically confirmed mCRC in liver, based on histopathology of prior section of primary lesion or a biopsied liver metastatic lesion (cannot be MSI-H) or metastatic NSCLC</li> <li>mCRC: primary lesions resected and received at least 2 regimens of 5-FU-based chemotherapy (e.g. FOLFOX, FOLFIRI, CAPOX, XELOX) + anti-VEGF/anti-EGFR</li> <li>Must have measurable disease; should also have at least one liver target tumor lesions with diameter of &gt;2 cm and amenable for TATE. Patients should also have one measurable non-hepatic lesion.</li> </ul>	Open to accrual
Dr. Dayyani	Krissy Ghio	UCI 21-110: Phase Ib/II Study of Agents Targeting the Mitogen-Activated Protein Kinase Pathway in Patients with Advanced Gastrointestinal Malignancies (HERKULES-3)	anti-ERK1/2 + Cetuximab + Encorafenib	<ul style="list-style-type: none"> <li>Histologically or cytologically confirmed metastatic CRC</li> <li>Dose Escalation cohorts: must have disease progression after at least 1 systemic regimen. Prior regimens must contain the following (prior regorafenib or TAS-102 prohibited): <ul style="list-style-type: none"> <li>All patients: 5-FU or capecitabine, oxaliplatin and/or irinotecan, bevacizumab</li> <li>Patients with MSI-H or dMMR CRC: pembrolizumab or nivolumab</li> </ul> </li> <li>Please contact clinical research coordinator for latest cohort status and updates</li> </ul>	Open to accrual
Dr. Chow	My Ha 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	anti-DR5 targeting pentameric Igm antibody IGM-8444	<p>Inclusion:</p> <p>Dose Escalation</p> <ul style="list-style-type: none"> <li>Histologic or cytologic documentation of incurable, locally advanced, or metastatic cancer who are refractory/intolerant to standard therapy or who have no further standard therapy</li> <li>No more than three prior therapeutic regimens</li> </ul> <p>Exclusion:</p> <ul style="list-style-type: none"> <li>Prior DR5 agonist therapy</li> <li>Prior DR5 agonist therapy</li> </ul>	Open to accrual

Metastatic Colorectal - Recurrent					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Cho	TBD	UCI 22-131: A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects with Metastatic Colorectal Cancer	small molecule inhibitor of several RTKs including MET, VEGFR2, AXL, and MER; anti-PD-L1; multi-kinase inhibitor	<ul style="list-style-type: none"> <li>Documented RAS status (mutant or WT), by tissue-based analysis</li> <li>No microsatellite instability-high (MSI-high) or mismatch repair deficient (dMMR) CRC</li> <li>Has received the following SOC anticancer therapies as prior therapy for metastatic CRC and has radiographically progressed, is refractory or intolerant to these therapies.</li> </ul> <p>a. Systemic SOC anticancer therapy must include ALL of the following agents:</p> <p>i. Fluoropyrimidine, irinotecan and oxaliplatin, with or without an anti-vascular endothelial growth factor (VEGF) monoclonal antibody (eg, bevacizumab)</p> <p>ii. Anti-epidermal growth factor receptor (EGFR) monoclonal antibody (eg, cetuximab or panitumumab) for RAS wild-type (WT) subjects</p> <p>iii. BRAF inhibitor for subjects with known BRAF V600E mutations <li>Radiographic progression during treatment with or within 3 months following the last dose of the most recent approved SOC chemotherapy regimen</li> </p>	Pending activation
Dr. Dayyani	TBD	UCI 22-213: An Open-Label, Multicenter, Phase 1b/2 Study of E7386 in Combination With Pembrolizumab in Previously Treated Subjects With Selected Solid Tumors	Wnt/ $\beta$ -catenin $\pm$ pembro $\pm$ lenvatinib	<ul style="list-style-type: none"> <li>Phase 1: Melanoma, HCC, and CRC for which prior standard therapy has failed</li> <li>Phase 2: <ul style="list-style-type: none"> <li>Melanoma: progressed after 1L of therapy containing one anti PD(L)1 (2L allowable if BRAF positive)</li> <li>CRC: progressed after 2L - 4L of therapy containing a fluoropyrimidine, irinotecan, and EGFR or BRAF if RAS wt or BRAF mutated</li> <li>HCC: progressed on only 1L of therapy in local/metastatic setting containing PD(L)1</li> </ul> </li> </ul>	Pending activation
Dr. Ou	Keagan 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	KRAS Inhibitor	<ul style="list-style-type: none"> <li>Pathologically documented, locally advanced or metastatic malignancy with KRASG12A, KRASG12D, KRASG12R, KRASG12S, or KRASG12V mutations</li> <li>Must have disease progression after treatment with fluoropyrimidine, oxaliplatin, and irinotecan. If MSI-H or MMRd, must have received nivolumab or pembrolizumab</li> <li>Subjects who have had prior therapy with any direct RAS inhibitor</li> </ul>	Pending activation
Intra-operative Colorectal					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Carmichael	My Ha Nguyen	UCI 20-163: Efficacy and Safety of the CG-100 Intraluminal Bypass Device in Colorectal and Coloanal Anastomoses: Prospective, Open Label, Randomized Trial	CG-100 Intraluminal Bypass Device	<ul style="list-style-type: none"> <li>Patients diagnosed with colorectal cancer who are 22-65 years of age at screening</li> <li>Scheduled for elective surgery (open, laparoscopic or robotic with mesorectal excision, either abdominal or transanal approach) which requires the creation of an anastomosis, max. 10 cm from anal verge</li> </ul>	Suspended

Anal Carcinoma					
Newly Diagnosed Anal Carcinoma					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Zell	Krissy Ghio	ECOG-EA2182: A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)	Standard dose vs de-intensified chemoradiation	<ul style="list-style-type: none"> <li>Histologically proven T1-2N0M0 invasive anal canal or anal margin squamous cell carcinoma; tumors measuring &lt; 4 cm within 4w prior to registration</li> </ul>	Open to accrual
Advanced/Metastatic Anal Carcinoma					
Dr. Cho	Krissy Ghio	ECOG-EA2176: A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients	Carboplatin + paclitaxel ± nivolumab	<ul style="list-style-type: none"> <li>Inoperable, recurrent, or metastatic anal squamous cell carcinoma (includes basaloid and cloacogenic lesions)</li> <li>Must have measurable disease per RECIST v1.1</li> <li>Palliative radiation therapy allowed as long as the treated lesion is not a target lesion</li> <li>HIV-infected patients on effective anti-retroviral therapy with undetectable viral load are eligible</li> </ul>	Open to accrual

Gastric and Gastroesophageal (GEJ)					
Gastric and GEJ - Neoadjuvant					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Dayyani	Amber Luna	UCI 21-191: Response Adopted Neoadjuvant Therapy in Gastroesophageal Cancers (RANT-GC Trial)	SOC therapy with ctDNA testing	<ul style="list-style-type: none"> <li>Histologically or cytologically confirmed adenocarcinoma of the stomach or gastroesophageal junction. Other GE histologies which are treated per NCCN guidelines for neoadjuvant treatment are eligible.</li> <li>Stage IB, II, or III disease eligible for (neo)adjuvant doublet or triplet chemotherapy for up to 6 months</li> <li>Baseline ctDNA assay must be positive (tested by Signatera) prior to initiation of neoadjuvant chemotherapy</li> </ul>	Pending activation
Gastric and GEJ - Newly Diagnosed Metastatic					
Dr. Senthil	Luisa Mejia Aguilar	UCI 20-87: Phase II Trial of Sequential Systemic Therapy Plus Intraperitoneal Paclitaxel in Gastric/GEJ Cancer Peritoneal Carcinomatosis	IV Paclitaxel + IV 5-FU + IV leucovorin + IP paclitaxel	<ul style="list-style-type: none"> <li>Histologically/cytologically confirmed GEJ adenocarcinoma</li> <li>Have received minimum of 3 months of 1st line systemic treatment without visceral metastatic progression</li> </ul>	Open to accrual
Dr. Dayyani	Luisa Mejia Aguilar	UCI 22-76: A Randomized, Open-Label, Multicenter Phase III Trial of Domvanalimab, Zimberelimab, and Chemotherapy Versus Nivolumab and Chemotherapy in Participants with Previously Untreated Locally Advanced Unresectable or Metastatic Gastric, Gastroesophageal Junction, and Esophageal Adenocarcinoma	anti-PD-1 + chemo +/- anti-TIGIT	<ul style="list-style-type: none"> <li>Cannot have known HER-2-positive tumor</li> <li>No prior systemic treatment for locally advanced unresectable or metastatic gastric, GEJ, or esophageal adenocarcinoma</li> <li>No disease progression within 6 months of neoadjuvant or adjuvant chemotherapy</li> </ul>	Pending activation

Gastric and GEJ - Recurrent					
Dr. Dayyani	My Ha Nguyen	UCI 21-193: A Phase IB/III Study of Bemarituzumab Plus Chemotherapy and Nivolumab Versus Chemotherapy and Nivolumab Alone in Subjects with Previously Untreated Advanced Gastric and Gastroesophageal Cancer with FGFR2b Overexpression	FGF inhibitor + mFOLFOX6 + anti-PD-L1 (nivolumab)	<ul style="list-style-type: none"> <li>Histologically documented gastric or gastroesophageal junction adenocarcinoma</li> <li>Unpreviously treated disease that is unresectable, locally advanced, or metastatic</li> <li>Measurable disease or non-measurable, but evaluable disease, per RECIST v1.1</li> <li>FGFR2b overexpression as determined by central testing</li> </ul>	Open to accrual
Dr. Dayyani	TBD	UCI 23-78: Phase II Study of Amivantamab in EGFR or MET- Amplified Esophagogastric Cancer	EGFR and MET-directed antibody	<ul style="list-style-type: none"> <li>Must have received at least 1 line of therapy</li> <li>EGFR or MET amplification</li> <li>No prior receipt of an EGFR or MET inhibitor for esophagogastric cancer</li> <li>Patients with HER2+ (IHC 3+ or IHC 2+/FISH+) tumors must have progressed on trastuzumab</li> </ul>	Pending activation
Dr. Dayyani	Luisa Mejia Aguilar	UCI 18-124: Phase 2 Study of Cabozantinib Combined with Pembrolizumab in Metastatic Gastric and Gastroesophageal Adenocarcinoma	Tyrosine Kinase inhibitor Cabozantinib and Anti-PD-1 Inhibitor Pembrolizumab	<ul style="list-style-type: none"> <li>2nd or 3rd line treatment</li> <li>Progression after at least one line of platinum and FU-containing regimen</li> </ul>	Open to accrual

Other					
Advanced Solid Tumors					
PI	CRC	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Nagasaka	Keagan Buttigieg 714-456-7429	UCI 19-57: 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	MET/CSF1R/SRC Inhibitor	Dose Escalation Phase: <ul style="list-style-type: none"> <li>Histological or cytological confirmation of advanced/metastatic solid tumors</li> <li>MET alteration(s) including exon 14 deletion (METΔex14), amplification, fusion or activating kinase mutation</li> <li>Resistant or intolerant to standard therapy or for whom curative therapy is not available</li> </ul>	Open to accrual
Dr. Valerin	My Ha 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	Anti-PD-1 DF1001 (monotherapy or combination therapy)	Dose Escalation Phase: Histologically/cytologically-proven locally advanced or metastatic solid tumors for which no standard therapy exists or standard therapy has failed <ul style="list-style-type: none"> <li>HER2 expression by IHC and/or erbb2 amplification and/or erbb2-activating mutations</li> </ul> Dose Expansion Phase: <ul style="list-style-type: none"> <li>UBC Cohort: must have received only 1L platinum-containing regimen for inoperable locally advanced/metastatic urothelial carcinoma with PD/recurrence &lt; 6 months after the last dose</li> <li>MBC Cohort: no more than 3 prior lines of cytotoxic therapy for metastatic disease</li> <li>Basket (HER2 3+) Cohort: HER2 3+ from biopsy &lt; 6 months</li> <li>Pembrolizumab Expansion Cohort: must be eligible to receive pembrolizumab per its label for a malignancy of epithelial origin (participants with prior pembrolizumab are excluded)</li> </ul>	Open to accrual
Dr. Pakbaz	Chidiebere Udechukwu	UCI 20-127: A Phase III Randomized Placebo controlled Double-Blind Study of Romiplostim for the Treatment of Chemotherapy-Induced Thrombocytopenia in Patients Receiving Oxaliplatin-based Chemotherapy for Treatment of Gastrointestinal, Pancreatic, or Colorectal Cancer	Romiplostim/placebo for chemotherapy-induced thrombocytopenia	<ul style="list-style-type: none"> <li>Histologically or cytologically confirmed diagnosis of gastrointestinal, pancreatic, or colorectal adenocarcinoma</li> <li>Subjects must be receiving one of the following regimens: an oxaliplatin-based chemotherapy regime, containing 5-FU or capecitabine plus oxaliplatin on a 14- or 21-day schedule, respectively</li> <li>Subjects must have a platelet count of &lt;75 x 10<sup>9</sup>/L on study day 1</li> <li>Must be at least 14 days removed from the start of the chemotherapy cycle immediately prior to study day 1 if they received FOLFOX, FOLFIRINOX, or FOLFOXIRI; 21 days removed if they received CAPEOX</li> </ul>	Open to accrual



Other					
Advanced Solid Tumors					
Dr. Ou	Richard 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
Dr. Kalebastay	Madina Popal 714-509-2951	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	SHP2 inhibitor	Dose Escalation Phase: • Diagnosis of advanced (primary or recurrent) or metastatic solid tumor with MAPK-pathway alterations (excluding BRAF V600X) Dose Expansion Phase: • Advanced or metastatic KRAS G12C of NSCLC or non-NSCLC with no available standard of care or curative therapies • Advanced or metastatic solid tumor with other MAPK-pathway alterations (excl. BRAF V600X) with no available standard of care or curative therapies	Open to accrual
Dr. Dayyani	Jasmine Balangue	UCI 21-10: A Phase I Dose-Escalation and Dose Expansion Study of TJ033721 in Subjects with Advanced or Metastatic Solid Tumors	Bispecific antibody (anti-CLDN18.2 + anti-4-1BB)	Dose Escalation Phase: • Histologically confirmed advanced or metastatic solid tumor whose disease has progressed despite standard therapy, or who has no further standard therapy, or is unsuitable for available standard treatment options • Subjects with HER2-positive GEJ cancer must have received prior anti-HER2 therapy • At least 1 measurable lesion per RECIST 1.1	Open to accrual

Other					
Advanced Solid Tumors					
Dr. Nagasaka	Jenny Choe 714-509-2522	UCI 21-53: A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	KRAS-G12C inhibitor	<ul style="list-style-type: none"> <li>Measurable disease per RECIST v1.1; evidence of KRAS G12C in tumor tissue or ctDNA</li> <li>Phase 1a Dose Escalation: patients must have progressed through or be intolerant to all therapies known to confer clinical benefit, or have refused therapy</li> </ul>	Open to accrual
Dr. Parajuli	Kristen Mueller	UCI 21-57: A Phase Ib/II, 2-Part, Open-Label Study to Assess the Safety and Antitumor Activity of Zanidatamab in Combination with ALX148 in Advanced HER2-Expressing Cancer	Bispecific antibody (anti-HER2) + CD47-blocking infusion protein	<ul style="list-style-type: none"> <li>Locally advanced and/or metastatic HER2-expressing cancer as follows: Parts 1 and 2: HER2-positive breast cancer, HER2-low breast cancer Part 2 (Cohort 3): HER2-positive gastroesophageal adenocarcinoma; other HER2-overexpressing non-breast cancers</li> <li>Progression after or during most recent systemic treatment for advanced cancer</li> </ul>	Open to accrual
Dr. Dayyani	Miranda 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	anti-Tissue Factor monoclonal antibody-BCN-vcMMAE conjugate	<ul style="list-style-type: none"> <li>Unresectable or metastatic cancer with disease progression during prior therapy, or relapse or progression following approved standard therapy for their tumor types (Part A: solid tumors, Part B: pancreatic, cervical, endometrial, bladder, TNBC)</li> <li>Measurable disease per RECIST v1.1</li> <li>For Part B patients: documented Tissue Factor (TF) presence in tumor biopsy specimens, obtained from archival or re-biopsy specimens by IHC</li> </ul>	Open to accrual
Dr. Dayyani	Nicole 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	<ul style="list-style-type: none"> <li>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</li> <li>Measurable or evaluable disease per RECIST v1.1 criteria</li> <li>Exclusion: Known brain metastases, spinal cord compression, carcinomatous meningitis or leptomeningeal disease unless appropriately treated and neurologically stable for &gt; 4 weeks</li> </ul>	Open to accrual
Dr. Tewari	Nirali Patel	UCI 22-78: A Phase 1 Study of KSQ-4279 Alone and in Combination in Patients With Advanced Solid Tumors	USP1 inhibitor	<ul style="list-style-type: none"> <li>Have a deleterious mutation (germline or somatic) in at least 1 of the following genes involved in the HRR pathway (BRCA1, BRCA2, PALB2, RAD51, RAD51B, RAD51C, RAD51D, BARD1, BRIP1, FANCA, and NBN)</li> <li>Histologically or cytologically confirmed locally advanced (unresectable) or metastatic solid tumors who meet one of the following criteria (Dose escalation only): a) relapsed or progressed through standard therapy b) Have a disease for which no standard effective therapy exists c) Not a candidate for standard effective therapy</li> </ul>	Open to accrual

Other					
Advanced Solid Tumors					
Dr. Dayyani	Peter Yang	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 buccal film vs. IV Palonosetron	<p><b>Inclusion :</b></p> <ul style="list-style-type: none"> <li>Chemotherapy naïve subjects with histologically or cytologically confirmed malignant disease; or chemotherapy non-naïve subjects with histologically proven diagnosis of cancer;</li> <li>Must be scheduled to receive an antineoplastic agent on cycle 1 day 1</li> </ul> <p><b>Exclusion:</b></p> <ul style="list-style-type: none"> <li>Experienced nausea (moderate to severe or vomiting following any previous chemotherapy)</li> </ul>	Pending activation
Dr. Ou	Richard 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	Tri-complex inhibitor KRAS <sup>G12C</sup> (ON) and NRAS <sup>G12C</sup> (ON)	<p><b>Inclusion:</b></p> <ul style="list-style-type: none"> <li>Must have locally advanced or metastatic KRAS<sup>G12C</sup> mutated solid tumor malignancy (not amenable to curative surgery) that has previously been treated with BOTH immunotherapy either given concurrently or sequentially for NSCLC; fluoropyrimidine, oxaliplatin, and irinotecan, with nivolumab or pembrolizumab for subjects with microsatellite unstable/mismatch clinically accredited laboratory testing using DNA sequencing or PCR test prior to this study.</li> <li>For Part 1 (Dose Escalation): Subjects with any KRAS<sup>G12C</sup>.</li> <li>For backfill cohorts of Part1 - Dose Escalation, only subjects with a KRASG12C-mutant tumor who have not been previously exposed to a KRASG12C inhibitor (KRASG12Ci-naïve) will be enrolled. Backfill cohorts may open enrollment to subjects with KRASG12C NSCLC with prior exposure to KRASG12C(OFF) inhibitor if a partial response (PR) or better to RMC-6291 is observed in this subject population during dose escalation</li> <li>For Part 2 - Dose Expansion, subjects with KRASG12C NSCLC and CRC who are KRASG12Ci-naïve will be enrolled</li> </ul> <p><b>Exclusion:</b></p> <ul style="list-style-type: none"> <li>Subjects has primary central nervous system (CNS) tumors.</li> </ul>	Open to accrual

Other					
Advanced Solid Tumors					
Dr. Chow	My Ha 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	anti-DR5 targeting pentameric Igm antibody IGM-8444	<p>Inclusion:</p> <p>Dose Escalation</p> <ul style="list-style-type: none"> <li>• Histologic or cytologic documentation of incurable, locally advanced, or metastatic cancer who are refractory/intolerant to standard therapy or who have no further standard therapy</li> <li>• No more than three prior therapeutic regimens</li> </ul> <p>Exclusion:</p> <ul style="list-style-type: none"> <li>• Prior DR5 agonist therapy</li> <li>• Prior DR5 agonist therapy</li> </ul>	Open to accrual

Other					
Advanced Solid Tumors					
Dr. Chow	Baoan Huynh	UCI 21-247: A First-in-Human, Multicenter, Open-Label, Phase 1 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-recombinant monoclonal anti-BTLA antibody monotherapy	<p>Inclusion:</p> <ul style="list-style-type: none"> <li>In Part A, patients must have received, or be ineligible for or intolerant of all available approved or standard therapies known to confer clinical benefit including immunotherapy, or for whom no standard therapy exists</li> <li>In Part B, patients with advanced or metastatic lymphoma, melanoma, NSCLC, or other tumors with agreement of the Sponsor, who must have received at least one line of therapy for advanced or metastatic disease, but are not required to have received all standard therapies known to confer clinical benefit.</li> <li>In Part C, patients must have received at least one line of therapy for advanced or metastatic disease but are not required to have received all standard therapies known to confer clinical benefit.</li> <li>In Part D, patients with advanced or metastatic lymphoma, melanoma, NSCLC, RCC or UC who must have received at least one line of therapy for advanced or metastatic</li> </ul> <p>Exclusion:</p> <ul style="list-style-type: none"> <li>Prior exposure to anti-BTLA or anti-HVEM antibodies for patients enrolled into part A or B. In all four parts, prior treatment with anti-PD-1 or anti-PD-L1 is allowed including toripalimab.</li> <li>Current or prior use of immunosuppressive medication equivalent to 10 mg/day of prednisone or its equivalent within 2 weeks prior to first dose of study drug</li> </ul>	Open to accrual
Dr. 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	Anti-PD-1 +/- DF9001	<p>Dose Escalation:</p> <ul style="list-style-type: none"> <li>documented EGFR expression</li> <li>progressed on standard of care therapy</li> <li>Evidence of objective disease, but participation does not require a measurable lesion.</li> </ul> <p>Dose Expansion:</p> <ul style="list-style-type: none"> <li>CRC, Esophageal adenocarcinoma, Gastric cancer</li> <li>measurable disease</li> </ul>	Pending activation

Other					
Advanced Solid Tumors					
Dr. Dayyani	Jasmine Balangue	UCI 22-38: A Phase 1b/2, Multicenter, Open-label Basket Study Evaluating the Safety and Efficacy of Bemarituzumab Monotherapy in Solid Tumors with FGR2b Overexpression (FORTITUDE-301)	Bemarituzumab (AMG 552)-FGFR2b inhibitor	<p>Inclusion:</p> <ul style="list-style-type: none"> <li>Histologically or cytologically confirmed cancer refractory to or relapsed after at least 1 prior standard therapeutic regimen in the advanced/metastatic setting, as specified: colorectal adenocarcinoma: &gt; or = 2 lines of therapy</li> <li>Tumor overexpresses FGFR2b as determined by centrally performed immunohistochemistry (IHC) testing</li> </ul> <p>Exclusion:</p> <ul style="list-style-type: none"> <li>Prior treatment with any investigational selective inhibitor of the FGF-FGFR pathway (unless approved standard of care for tumor indication)</li> <li>Untreated or symptomatic central nervous system (CNS) metastases or leptomeningeal disease</li> </ul>	Open to accrual
Dr. Dayyani	TBD	UCI 22-37: A Phase 1a/1b open-label study to assess the safety, pharmacokinetics, and antitumor activity of oral TACH101 in patients with advanced or metastatic solid tumors	inhibitor of KDM4 histone demethylase	<ul style="list-style-type: none"> <li>Phase 1a: Patient must have advanced or metastatic solid tumor that has progressed or was nonresponsive or intolerant to available therapies and for which no standard or available curative therapy exists</li> <li>Phase 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 (e.g., fluoropyrimidine and oxaliplatin with or without bevacizumab)</li> <li>No prior gastrectomy or upper bowel removal or any other gastrointestinal disorder that would interfere with the absorption or excretion of TACH101</li> </ul>	Pending activation
Dr. Valerin	TBD	UCI-22-75: First in Human Phase 1/2 Trial of ELI-002 7P Immunotherapy as Treatment for Subjects with Kirsten Rat Sarcoma (KRAS)/Neuroblastoma RAS Viral Oncogene homolog (NRAS) Mutated Solid Tumors	KRAS targeted Vaccine	<ul style="list-style-type: none"> <li>Histologically/cytologically confirmed solid tumor, centrally tested for RAS mutation</li> <li>Following chemotherapy and surgical resection, subject must have RO or R1 margins and radiographic NED</li> <li>Phase I: high risk of relapse evidenced by positive ctDNA or high/rising tumor markers</li> </ul>	Pending activation

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Other Correlative, Basic Science, Observational)					
PI	CR	Protocol No. and Title	Mechanism	Primary Inclusion/Exclusion Criteria	Status
Dr. Imagawa	Spencer Ninofranco	UCI 03-03: Immunologic Factors Affecting Outcomes in Patients with Liver Cancer	Immunologic response analysis	<ul style="list-style-type: none"> <li>Primary or metastatic liver cancer, scheduled for surgery with Dr. Imagawa or Dr. Demirjian</li> </ul>	Open to accrual
Dr. Jutric	Spencer Ninofranco	UCI 08-70: Establishment of a multidisciplinary pancreatic tumor biorepository and integrated clinical database	Biobank	<ul style="list-style-type: none"> <li>Pancreatic lesion suspicious of cancer</li> </ul>	Open to accrual
Dr. Dayyani	My Ha Nguyen	UCI 19-55: A Non-Interventional Biomarker Study on the Molecular Evaluation of Archival Tumor Tissue in Subjects with Gastric Cancer	MUC17 and CLDN18.2 tissue testing	<ul style="list-style-type: none"> <li>Archival tumor tissue sample for central lab for MUC17 and CLDN18.2 testing</li> <li>Locally advanced or metastatic gastric adenocarcinoma at time of enrollment: T2-T4b/N0-3b/M0-M1</li> <li>See: UCI 19-56 for companion interventional study</li> </ul>	Open to accrual
Dr. Waterman	Spencer Ninofranco	UCI 20-04: University of California Minority Patient-Derived Xenograft (PDX) Development and Trial Center (UCaMP) to Reduce Cancer Health Disparities	Tissue collection	<ul style="list-style-type: none"> <li>Patient receiving treatment for the above 4 cancers (bladder cancer, lung cancer, gastric/stomach cancer, and liver cancer)</li> </ul>	Open to accrual
Dr. Senthil	Corrinne Maton	UCI 20-101: Prospective Study to Assess the Role of Plasma Exosomal PD-L1 to Predict Response to Immune Checkpoint Inhibition in Melanoma and Solid Organ Malignancies	Biospecimen collection for patients planned to start treatment	<ul style="list-style-type: none"> <li>Must have immunotherapy-naïve histologically, radiologically, or cytologically confirmed cancer (e.g. melanoma, HCC, colorectal, appendix or gastric cancer)</li> <li>Must have measurable disease at time of enrollment</li> </ul>	Open to accrual
Dr. Abi-Jaoudeh	Natalie Arechiga	UCI 21-103: Registry to Evaluate Effectiveness and Safety of the NanoKnife System for the Ablation of Stage 3 Pancreatic Adenocarcinoma	Registry study	<ul style="list-style-type: none"> <li>Cytologically or pathologically confirmed stage 3 pancreatic carcinoma</li> <li>Maximum axial and anterior to posterior tumor dimension of &lt;3.5 cm after SOC</li> <li>Patient has received 3 months of SOC therapy per institution's guidelines; no evidence of disease progression</li> <li>Patient must be deemed eligible for IRE and receive ablation using the NanoKnife system</li> </ul>	Open to accrual
Dr. Abi-Jaoudeh	Natalie Arechiga	UCI 21-124: Pilot Trial Comparing Circulating Tumor DNA (ctDNA) From Immediate Draining Vein vs. Standard Peripheral Vein Sample in Patients Undergoing Biopsies for Hepatobiliary and Pancreatic Cancers	Comparison of ctDNA in draining vein plasma vs. peripheral vein sample.	<ul style="list-style-type: none"> <li>Have or are undergoing work-up for hepatobiliary and/or pancreatic carcinoma</li> <li>Scheduled for image-guided percutaneous or transjugular biopsy of a lesion</li> <li>Excluded: patients who cannot have a peripheral blood draw for ctDNA</li> </ul>	Open to accrual