UCI Chao Family Comprehensive Cancer Center

Gastrointestinal Clinical Trials

Colorectal					
Neoadjuvant Colorectal					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Zell	Krissy Ghio	EA2182: A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)	Standard dose vs de-intensified chemoradiation	• Histologically proven T1-2N0M0 invasive anal canal or anal margin squamous cell carcinoma; tumors measuring < 4 cm within 4w prior to registration	Open to accrual
Dr. Zell	Krissy Ghio	UCI 20-09: Short Course Radiation and TASOX (TAS102 plus Oxaliplatin) Chemotherapy in Operable Rectal Cancer, a Phase II Trial	Radiation + neoadjuvant TASOX; surgery	• Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0 • Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy	Pending activation
Adjuvant Colorectal					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Zell	Dorothy Chang	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	• Stage 0-III colon or rectal adenocarcinoma treated per SOC with resection alone or in combination with radiation or chemotherapy • Registration within 180-456 (inclusive) days of primary resection • NED (post-operative colonoscopy)	Open to accrual
Dr. Zell	Krissy Ghio	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	• Histologically/pathologically confirmed stage IIA adenocarcinoma of the colon (T3, N0, M0) with at least 12 lymph nodes examined at time of resection • Appropriate for active surveillance (e.g. no planned adjuvant chemotherapy) at discretion of and as documented by treating oncologist • Distal extent of tumor > 12 cm from anal verge on pre-surgical endoscopy or determined by surgical exam/pre-op imaging	Open to accrual
Dr. Dayyani	Bao Huynh	UCI 20-03: BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer (CRC)	ctDNA-guided therapy after surgery	• Undergone surgery for stage II/III colorectal cancer with available tissue & whole blood samples • Using SIGNATERA test, may be recommended for adjuvant chemotherapy or observation by treating physician	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	• Adenocarcinoma of colon (high rectal cancer eligible if resected and no radiation needed) • Stage II or III colorectal cancer eligible for adjuvant doublet chemotherapy for 6 months • Must be ctDNA+ (tested by Signaterra MRD assay) after 3 months of adjuvant chemotherapy	Open to accrual
Metastatic Colorectal - Newly Diagnosed					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Cho	Krissy Ghio	EA2176: A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients	Carboplatin + paclitaxel ± nivlumab	• Inoperable, recurrent, or metastatic anal squamous cell carcinoma (includes basaloid and cloacogenic lesions) • Must have measurable disease per RECIST v1.1 • Palliative radiation therapy allowed as long as the treated lesion is not a target lesion • HIV-infected patients on effective anti-retroviral therapy with undetectable viral load are eligible	Pending activation

Contact Information:
Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
Cindy Duong 714-509-2740 | duongca@hs.uci.edu
Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Gastrointestinal Clinical Trials

Metastatic Colorectal - Recurrent					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Jasmine Balangue	UCI 20-134: Phase I Study of Cabozantinib Plus TAS102 in mCRC as Salvage Therapy	Cabozantinib + TAS102	• Histologically or cytologically confirmed colorectal adenocarcinoma • Locally advanced, recurrent, or metastatic disease not amenable to curative surgery or radiation • Must have progressed, or not tolerated, a fluoropyrimidine, irinotecan, oxaliplatin, and cetuximab or panitumumab (only for RAS wild-type). Prior exposure to bevacizumab or ramucirumab is allowed. • Patients who have exhausted all other SOC options are also eligible	Open to accrual
Dr. Abi-Jaoudeh	Cindy Duong	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	• 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 • 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 • Must have measurable disease; should also have at least one liver target tumor lesions with diameter of >2 cm and amenable for TATE. Patients should also have one measurable non-hepatic lesion.	Open to accrual
Dr. Dayyani	TBD	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	• Histologically or cytologically confirmed metastatic CRC • **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): - All patients: 5-FU or capecitabine, oxaliplatin and/or irinotecan, bevacizumab - Patients with MSI-H or dMMR CRC: pembrolizumab or nivolumab • Please contact clinical research coordinator for latest cohort status and updates	Pending activation
Intra-operative Colorectal					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Carmichael	Jasmine Balangue	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	• Patients diagnosed with colorectal cancer who are 22-65 years of age at screening • 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 • Scheduled to receive protective stoma under routine clinical practice during primary planned operation; scheduled to undergo mechanical bowel preparation	Open to accrual
Post-operative Colorectal					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Carmichael	Ana Gonzalez Vargas *714-509-2698*	SWOG-S1820: A Randomized Phase II Trial of the Altering Intake, Managing Symptoms (AIMS-RC) Intervention for Bowel Dysfunction in Rectal Cancer Survivors	Telephone Diet Modification Coaching (AIMS-RC) vs Telephone Health Education	• Prior history of rectosigmoid colon or rectal cancer with post-surgical permanent ostomy or anastomosis • Last date of treatment for rectal cancer (surgery, chemo, RT) must be at least 6 months but no more than 24 months prior to registration • Anamatosis patients LARS score 21-42 within 5 calendar days of registration	Open to accrual

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Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
Cindy Duong 714-509-2740 | duongca@hs.uci.edu
Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Gastrointestinal Clinical Trials

Gastric and Gastroesophageal (GEJ)					
Gastric and GEJ - Newly Diagnosed					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Cindy Duong	UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	anti-CD39 ± anti-PD-1 and/or mFOLFOX6	• Cohort 12 (budigalimab + mFOLFOX6): HER2-negative gastric adenocarcinoma, chemo-naïve (first line treatment) • Measurable disease per RECIST v1.1	Open to accrual
Dr. Fachyi Lee	Cindy Duong	UCI 20-35: A Multicenter, Double-Blind, Randomized Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination with Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15)	Sintilimab + Cisplatin + Paclitaxel or 5-FU	• Histopathologically confirmed unresectable, locally advanced, recurrent or metastatic ESCC • Must be unsuitable for definitive treatment (e.g. definitive chemo RT and/or surgery) • For subjects who have received (neo)adjuvant or definitive chemo/chemo RT, time from completion of last treatment to disease recurrence must be >6 months	Open to accrual
Dr. Dayyani	Krissy Ghio	UCI 20-63: A Phase IIa, Multicenter, Open-Label Study of DKN-01 in Combination with Tislelizumab ± Chemotherapy as First-Line or Second-Line Therapy in Adult Patients with Inoperable, Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (DisTinGuish)	DKN-01 + tislelizumab ± CAPOX	• Part B will enroll patients who received only 1 prior systemic treatment, which must consist of a platinum + fluoropyrimidine–based therapy (±HER2 therapy if applicable) for locally advanced/metastatic DKK1-high G/GEJ adenocarcinoma (second-line treatment)	Open to accrual
Dr. Senthil	Jasmine Balangue	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	• Histologically/cytologically confirmed GEJ adenocarcinoma • Have received minimum of 3 months of 1st line systemic treatment without visceral metastatic progression	Open to accrual
Gastric and GEJ - Recurrent					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Krissy Ghio	UCI 18-124: Phase 2 Study of Cabozantinib Combined with Pembrolizumab in Metastatic Gastric and Gastroesophageal Adenocarcinoma	Cabozantinib and Pembrolizumab	• 2nd or 3rd line treatment • Progression after at least one line of platinum and FU-containing regimen	Open to accrual
Dr. Dayyani	Jasmine Balangue	UCI 19-56: A Phase I Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of the Half-life Extended Bispecific T-cell Engager AMG 199 in Subjects with MUC17-Positive Gastric Cancer	AMG199	• MUC17-positive (see UCI 19-55 for testing) • Refractory or relapsed after ≥2 lines of therapy	Open to accrual
Dr. Dayyani	Cindy Duong	UCI 20-77: An Open-Label, Multi-Center Phase I/II Dose Escalation and Expansion Study to Assess the Safety, Efficacy and Pharmacokinetics of MRG002 in Patients with HER2-Positive Advanced Solid Tumors and Locally Advanced or Metastatic Gastric/Gastroesophageal Junction (GEJ) Cancer	Anti-HER2	• Part A: must have histologically or cytologically confirmed HER2/ERBB2-positive metastatic, unresectable cancer • Must have prior disease progression on all standard therapies for their tumor • HER2-positive testing: HER2 IHC 3+ or HER2 IHC 2+/ISH-positive, or HER2/ERBB2-positive amplification on FFPE tumor sample by NGS	Open to accrual (Part A only)
Dr. Dayyani	Krissy Ghio	ETCTN-10211: A Phase II Single-Arm Study of M6620 in Combination with Irinotecan in Patients with Progressive TP53 Mutant Gastric and Gastro-Esophageal Junction Cancer	M6620 and Irinotecan	• TP53 positive • 2nd or 3rd line treatment • Progression after at least one line of trastuzumab and chemotherapy if HER2+ • Patients with MSI-H tumors must have received prior immunotherapy with pembrolizumab	Suspended
Post-operative Gastric and GEJ					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Carmichael	Carlos Chavez *714-456-5396*	UCI 19-40: A Randomized, Double-Blind, Placebo-Controlled, Phase II Dose Ranging Study to Evaluate the Efficacy and Safety of Two Dose Regimens of Intravenous TAK-954 for the Prophylaxis and Treatment of Postoperative Gastrointestinal Dysfunction in Patients Undergoing Large- and Small-Bowel Resection	TAK-954	• Scheduled to undergo laparoscopic-assisted or open partial small- or large-bowel resection	Suspended

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Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
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Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Gastrointestinal Clinical Trials

Liver					
Early Stage HCC - Adjuvant					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Krissy Ghio	UCI 19-36: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Durvalumab Monotherapy or in Combination With Bevacizumab as Adjuvant Therapy in Patients With Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation (EMERALD-2)	anti-PD-L1 + anti-VEGF	• HCC with completed curative therapy (resection or ablation) • Patients must be randomized within 12 weeks of completing curative therapy • Child-Pugh A5-A6	Open to accrual
Intermediate Stage HCC - Locoregional					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Cindy Duong	UCI 19-49: Phase II Study of Cabozantinib Combined with Ipilimumab/Nivolumab and Transarterial Chemoembolization (TACE) in Patients with Hepatocellular Carcinoma (HCC) Who are not Candidates for Curative Intent Treatment	Cabozantinib (TKI) + Ipi/nivo (IO) + TACE	• Histologic or radiographic HCC diagnosis, not a candidate for resection or transplantation • Child-Pugh A-B7 (B7 based on albumin allowed) • Must have at least one measurable lesion (untreated or progressed after previous local treatment)	Open to accrual
Dr. Imagawa	Cindy Duong	UCI 19-106: A Phase III Multicenter, Randomized, Double-blinded, Active-controlled, Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) with Pembrolizumab (MK-3475) in Combination with Transarterial Chemoembolization (TACE) versus TACE in Participants with Incurable/Non-Metastatic Hepatocellular Carcinoma (LEAP-012)	TACE + Lenvatinib/placebo (PO QD) + Pembrolizumab/placebo (IV q6w)	• 1st line treatment • Imaging confirmed HCC (no portal vein thrombosis) • Child-Pugh A • All lesions must be treatable in 1-2 (split-TACE) sessions	Open to accrual
Dr. Abi-Jaoudeh	Cindy Duong	UCI 20-84: Randomized Multi-Center, Subject and Evaluator Blinded, Parallel-Group Study to Evaluate the Safety and Effectiveness of the Instylla Hydrogel Embolic System (HES) Compared with Standard of Care Transcatheter Arterial Embolization (TAE) / Transcatheter Arterial Chemoembolization (cTACE) for Vascular Occlusion of Hypervascular Tumors; A Pivotal Study (INY-P-20-001)	Hydrogel embolic system vs SOC TAE/cTACE	• Subjects must be > 22 years old • CT/MRI-confirmed hypervascular tumor where TAE/cTACE is medically indicated, including but not limited to subjects with: 1) unresectable primary or metastatic hepatic cancer, 2) primary, metastatic, or benign renal tumors, 3) bone metastases, 4) adrenal tumors, 5) other hypervascular tumors • Must have at least one target lesion that is well-delineated, suitable for remeasurement, and demonstrates definitive arterial enhancement	Open to accrual
Advanced/Metastatic HCC - Newly Diagnosed					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Krissy Ghio	UCI 19-70: A Phase Ib/II, Open-Label, Study of Tivozanib in Combination with Durvalumab in Subjects with Untreated Advanced Hepatocellular Carcinoma	anti-PD-L1 + anti-VEGF	• 1st line systemic treatment • Child-Pugh A • Previous locoregional treatment: wash-out of 28 days prior to enrollment	Open to accrual
Dr. Dayyani	Cindy Duong	UCI 20-79: A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients with Advanced Liver Cancers (Morpheus Liver)	Stage 1: Atezo/beva vs atezo/beva + tiragolumab vs atezo/beva + tocilizumab	• 1st line systemic treatment • Histology/cytology confirmed locally advanced or metastatic and/or unresectable HCC • Child-Pugh A • Prior local therapy allowed (required: untreated measurable lesion or locally treated lesion must have progressed per RECIST)	Open to accrual

Contact Information:
Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
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Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Advanced/Metastatic HCC - Recurrent					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Abi-Jaoudeh	Pam Singh *714-456-8516*	UCI 16-94: Phase IIA Single-Arm Study of Treatment of Patients with Advanced Liver Cancer with a Combination of TATE (Transarterial Tirapazamine Embolization) Followed by an Anti- PD-1 Monoclonal Antibody	TATE in combination with checkpoint inhibitors nivolumab or pembrolizumab	• Metastatic colorectal cancer in liver or advanced HCC (BCLC C) • Prior therapy must be at least 4 weeks prior to enrollment and free from treatment-related toxicity	Suspended
Dr. Dayyani	Emiri Matsuda *714-509-2710*	UCI 20-103: An Open-Label, Dose Escalation, Multi-Center Phase I/II Research Trial to Assess the Safety of ET140203 T Cells and Determine the Recommended Phase II Dose (RP2D) in Adults with Advanced Hepatocellular Carcinoma (HCC)	ET140203 T-cells target and kill AFP-expressing HCC tumor cells	• Must have failed or not tolerated at least (2) different anti-HCC systemic agents • Subject must carry at least one HLA-A2 allele • HCC with serum AFP >200 ng/ml (biopsy-proven) or HCC with serum >400 ng/ml (based on imaging)	Open to accrual
Dr. Dayyani	Cindy Duong	UCI 20-162: An Open-Label Study of Regorafenib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Hepatocellular Carcinoma (HCC) after PD-1/PD-L1 Immune Checkpoint Inhibitors	Multikinase inhibitor + anti-PD-1	• 2nd line systemic treatment • Must have had prior 1L immunotherapy treatment with PD(L)-1 checkpoint inhibitor • Histological/cytological confirmation of unresectable advanced HCC or imaging confirmed HCC per AASLD criteria for cirrhotic participants • Progressive disease must have been documented within 12 weeks from last dose of 1L therapy • Child-Pugh A; BCLC stage B or C	Open to accrual

Pancreas					
Borderline Resectable or Locally Advanced Pancreatic					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Krissy Ghio	ETCTN-10366: A Phase I/II Study of M3814 (Peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma	M3815 (peposertib) and radiation therapy	• Locally advanced pancreatic adenocarcinoma • Received 4-6 months of induction chemotherapy with either FOLFIRINOX or gemcitabine/abraxane, as per SOC	Open to accrual
Dr. Imagawa	Cindy Duong	UCI 18-10: PACER (Pancreatic AdenoCarcinoma with Electron Intraoperative Radiation Therapy): A Phase II Study of Electron Beam Intraoperative Radiation Therapy Following Chemoradiation in Patients with Pancreatic Cancer with Vascular Involvement	Intraoperative radiation therapy	• Borderline/potentially resectable or locally advanced pancreatic adenocarcinoma • Previous completion of gemcitabine + nabpaclitaxel or FOLFIRINOX • Previous completion of SBRT or chemoradiation	Open to accrual
Metastatic Pancreatic - Newly Diagnosed					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Valerin	Jasmine Balangue	EA2186: A Randomized Phase II Study of Gemcitabine and NabPaclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)	Irinotecan liposome + leucovorin + 5-FU vs Gem + Abraxane	• 1st line systemic treatment for metastatic pancreatic adenocarcinoma • ≥ 70 years old	Open to accrual
Dr. Dayyani	Cindy Duong	UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	anti-CD39 + anti-PD-1 + gem/abraxane	• Cohort 11 (TTX-030 + gemcitabine/abraxane): Histolologically or cytologically confirmed diagnosis of locally advanced, unresectable, or metastatic pancreatic adenocarcinoma • Naïve to any prior treatment for metastatic disease (prior adjuvant therapy allowed if neoadjuvant/adjuvant and if completed > 6 months prior to enrollment) • Eligible to receive gemcitabine + nab-paclitaxel as standard of care	Open to accrual
Metastatic Pancreatic - Recurrent					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**

Contact Information:
Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
Cindy Duong 714-509-2740 | duongca@hs.uci.edu
Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Dr. Dayyani	Jasmine Balangue	ETCTN-10208: A Phase I study of Anetumab Ravtansine in Combination with either Anti-PD-1 Antibody, or Anti-CTLA4 and Anti-PD-1 Antibodies or Anti-PD-1 Antibody and Gemcitabine in Mesothelin-Positive Advanced Pancreatic Adenocarcinoma	Anetumab Ravtansine w/immunotherapy and gemcitabine	• Positive for Mesothelin • Progressed or been intolerant to at least 1 systemic therapy	Open to accrual

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Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Gastrointestinal Clinical Trials

Other					
Advanced Solid Tumors					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. Dayyani	Cindy Duong	UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	TTX-030 (anti-CD39) + Anti-PD-1 and/or mFOLFOX6	• Cohort 12 (open): HER2-negative gastric adenocarcinoma, chemo-naïve (first line treatment) • Cohort 11 (open): Histolologically or cytologically confirmed diagnosis of locally advanced, unresectable, or metastatic pancreatic adenocarcinoma • Cohort 10 (open): Diagnosis of unresectable or metastatic UCC. Ineligible for cisplatin and PD(L)-1 CPS >10 or platinum-ineligible regardless of PD(L)-1 status or received prior adjuvant platinum-based chemo with disease recurrence >12 months since therapy completion	Open to accrual
Dr. Bota	Celine Colmenares *714-509-2172*	UCI 19-38: A Phase IA/IB, Open-Label First-in-Human Study of the Safety, Tolerability, and Feasibility of Gene-Edited Autologous NeoTCR-T Cells (NeoTCR-P1) Administered as a Single Agent or in Combination with Anti-PD-1 to Patients with Locally Advanced or Metastatic Solid Tumors	Gene-Edited Autologous NeoTCR-T Cells	• 2nd or 3rd line treatment • Metastatic solid tumor of the following types: melanoma, urothelial cancer, ovarian cancer, colorectal cancer, breast cancer (HR+), or prostate cancer	Open to accrual - **CRC cohort suspended**
Dr. Fachyi Lee	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: • Histological or cytological confirmation of advanced/metastatic solid tumors • MET alteration(s) including exon 14 deletion (METΔex14), amplification, fusion or activating kinase mutation • Resistant or intolerant to standard therapy or for whom curative therapy is not available	Suspended
Dr. Valerin	Jasmine 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 (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 • HER2 expression by IHC and/or erbb2 amplification and/or erbb2-activating mutations Dose Expansion Phase: • UBC Cohort: must have received only 1L platinum-containing regimen for inoperable locally advanced/metastatic urothelial carcinoma with PD/recurrence < 6 months after the last dose • MBC Cohort: no more than 3 prior lines of cytotoxic therapy for metastatic disease • Basket (HER2 3+) Cohort: HER2 3+ from biopsy < 6 months • Pembrolizumab Expansion Cohort: must be eligible to receive pembrolizumab per its label for a malignancy of epithelial origin (participants with prior pembrolizumab are excluded)	Open to accrual
Dr. Ou	Anabel Serwanska *714-456-8279*	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 • Advanced or metastatic (Stage IIIB or IV) or unresectable • 2nd or 3rd line treatment (no previous ERBB/HER2/HER3 treatment for cohort 1)	Open to accrual
Dr. Pakbaz	Kristen Mueller *714-509-2369*	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	• Histologically or cytologically confirmed diagnosis of gastrointestinal, pancreatic, or colorectal adenocarcinoma • 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 • Subjects must have a platelet count of <75 x 10^9/L on study day 1 • 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	Open to accrual

Contact Information:
Bao Huynh 714-509-6233 | baoanh1@hs.uci.edu
Cindy Duong 714-509-2740 | duongca@hs.uci.edu
Dorothy Chang 714-509-2199 | dorothc@hs.uci.edu
Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Other					
Advanced Solid Tumors					
Dr. Ou	Keagan Buttigieg *714-456-7429*	UCI 20-185: A Phase I/IB, Open-Label, Dose Escalation and Expansion Study of SBT6050 Alone and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Expressing HER2	SBT6050 (anti-HER2) ± pembrolizumab	Part 1 (Dose Escalation Phase): • HER2-expressing (IHC 2+ or 3+) or HER2-amplified advanced cancers Part 2 (Dose Expansion Phase) for Locally Advanced and/or Metastatic Cancers • Cohort A: HER2-positive (IHC 3+ or IHC2+/HER2 amplified) breast cancer • Cohort B: HER2-low-expressing (IHC 2+/HER2 non-amplified) breast cancer • Cohort C: HER2-positive (IHC 3+ or IH2+/HER2 non-amplified) gastric or GEJ cancer • Cohort D: HER2-expressing (IHC 3+ or 2+) or HER2-amplified NSCLC • Cohort E: Other HER22-expressing (IHC 3+ or 2+) or HER2-amplified malignant solid tumors Part 3 and 4 (Dose Expansion Phase) for Locally Advanced and/or Metastatic Cancers • HER2-positive (IHC 3+ or IHC 2+/HER2 amplified) breast cancer, gastroesophageal cancer • HER2-expressing (IHC 3+ or 2+) or HER2 amplified colorectal cancer, endometrial cancer, biliary tract cancer, cholangiocarcinoma, NSCLC, HNSCC, urothelial cancer	Open to accrual
Dr. Ou	Celest Ramirez *714-509-2738*	UCI 20-194: A Phase I/II, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of D-1553 in Subject with Advanced or Metastatic Solid Tumors with KRasG12C Mutation	D-1553 (KRAS inhibitor)	• Histologically-proven, locally advanced, unresectable and/or metastatic solid tumor • KRasG12C mutation in tumor tissue or blood, pleural effusion, or other samples containing cancer cells or DNA (Phase I - historical local lab results < 5 years may be used; Phase II - must be tested centrally)	Open to accrual
Dr. Ou	Keagan Buttigieg *714-456-7429*	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	Open to accrual
Dr. Ou	Anabel Serwanska *714-509-8279*	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. Rezazadeh	TBD	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	Pending activation

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Jasmine Balangue 714-509-2948 | balanguj@hs.uci.edu
Krissy Ghio 714-456-6258 | kghio@hs.uci.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hs.uci.edu

Other					
Advanced Solid Tumors					
Dr. Dayyani	Jasmine 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	anti-LILRB2 + anti-PD-1	• Currently enrolling in the following stages and cohorts: ***Stage 2: Combo JTX-8064 Escalatio** for solid Tumors ***Stage 3: Mono JTX-8064 Expansion** for Cohort 3C: 3rd line/4th line platinum-resistant **ovarian cancer**, must be PD-(L)-1-naïve ***Stage 4: JTX-8064 + JTX-4014** for Cohort 4A (2L/3L **ccRCC**), Cohort 4F (2L - 4L **triple negative BC**), Cohort 4H (1L **HNSCC**), Cohort 4K (2L/3L **NSCLC**), Cohort 4L (2L/3L **cSCC**), and Cohort 4M (2L - 4 L **UPS** and **LPS**) • Must have measurable disease per RECIST v1.1 • Pre-treatment biopsy required • For updates in enrollment stages and cohort-specific eligibility criteria, please contact the primary clinical research coordinator	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	Pending activation
Dr. Dayyani	Jasmine Balangue	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	Multiple kinase inhibitor	• Histopathological/cytologically documented locally advanced or metastatic solid tumors who have no available standard therapeutic treatment options • **Arm A:** cholangiocarcinoma, HER2-negative metastatic breast cancer, bladder cancer, small cell lung cancer, prostate cancer, thyroid cancer, sarcoma, gastric cancer, gallbladder cancer, and other advanced solid tumors • **Arm B:** patients with HER2-negative metastatic breast cancer who have not responded to standard of care treatments • At least one measurable lesion per RECIST v1.1	Pending activation
Dr. Ou	Gabriela Mamani *714-509-2431*	UCI 21-53: A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	KRAS-G12C inhibitor	• Measurable diseae per RECIST v1.1 • Evidence of *KRAS* G12C mutation in tumor tissue or ctDNA • Phase 1a Dose Escalation: patients must have progressed through or be intolerant to all therapies known to confer clinical benefit, or have refused therapy	Open to accrual
Dr. Parajuli	Ana Gonzalez Vargas *714-509-2698*	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	• 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 • Progression after or during most recent systemic treatment for advanced cancer • Measurable disease per RECIST v1.1	Pending activation
Dr. Dayyani	TBD	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	• 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) • Measurable disease per RECIST v1.1 • For Part B patients: documented Tissue Factor (TF) presence in tumor biopsy specimens, obtained from archival or re-biopsy specimens by IHC	Pending activation

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Gastrointestinal Clinical Trials

Other					
Non-Treatment Trials (Correlative, Basic Science, Observational)					
PI	**CRC**	**Protocol No. and Title**	**Mechanism**	**Primary Inclusion/Exclusion Criteria**	**Status**
Dr. O'Brien	Mashal Chhotani *714-509-2946*	NCICOVID: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study	Data, specimen, and image collection	• Actively undergoing cancer treatment (chemotherapy, targeted therapy, immunotherapy, and/or radiation therapy) or follow-up care treatment that requires regular visits to UCI Health - Orange or Newport • Must be currently testing for SARS-CoV-2 or has had first positive test < 14 days	Open to accrual
Dr. Imagawa	Chang Shim	UCI 03-03: Immunologic Factors Affecting Outcomes in Patients with Liver Cancer	Immunologic response analysis	• Primary or metastatic liver cancer, scheduled for surgery with Dr. Imagawa or Dr. Demirjian	Open to accrual
Dr. Jutric	Chang Shim	UCI 08-70: Establishment of a multidisciplinary pancreatic tumor biorepository and integrated clinical database	Biobank	• Pancreatic lesion suspicious of cancer	Open to accrual
Dr. Bristow	TBD	UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California	Health services research	• Adults diagnosed with colorectal, liver, stomach cancer	Pending activation
Dr. Dayyani	Jasmine Balangue	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	• Archival tumor tissue sample for central lab for MUC17 and CLDN18.2 testing • Locally advanced or metastatic gastric adenocarcinoma at time of enrollment: T2-T4b/N0-3b/M0-M1 • See: UCI 19-56 for companion interventional study	Open to accrual
Dr. Tanjasiri	TBD	UCI 19-101: Cancer Navigation for Vietnamese Americans (CANVAS)			Pending activation
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	• Patient receiving treatment for the above 4 cancers (bladder cancer, lung cancer, gastric/stomach cancer, and liver cancer)	Open to accrual
Dr. Senthil	Krissy Ghio	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	• Must have immunotherapy-naïve histologically, radiologically, or cytologically confirmed cancer (e.g. melanoma, HCC, colorectal, appendix or gastric cancer) • Must have measurable disease at time of enrollment	Open to accrual

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