## Gastrointestinal Clinical Trials

### Colorectal

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol No. and Title</th>
<th>Mechanism</th>
<th>Primary Inclusion/Exclusion Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Zell</td>
<td>Krissy Ghio</td>
<td>EA2182: A Randomized Phase II Study of De-Intensified Chemoradiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)</td>
<td>Standard dose vs de-intensified chemoradiation</td>
<td>• Histologically proven T1-2N0M0 invasive anal canal or anal margin squamous cell carcinoma; tumors measuring &lt; 4 cm within 4w prior to registration</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Zell</td>
<td>Krissy Ghio</td>
<td>UCI 20-09: Short Course Radiation and TASOX (TAS102 plus Oxaliplatin) Chemotherapy in Operable Rectal Cancer, a Phase II Trial</td>
<td>Radiation + neoadjuvant TASOX, surgery</td>
<td>• Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0 • Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy</td>
<td>Pending activation</td>
</tr>
<tr>
<td>Dr. Zell</td>
<td>Dorothy Chang</td>
<td>S0820: A Double Blind Placebo-Controlled Trial of Efornithine 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)</td>
<td>Ornithine decarboxylase (ODC) inhibitor + COX I/II inhibitor</td>
<td>• 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)</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Dayyani</td>
<td>Bao Huynh</td>
<td>UCI 20-03: BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer (CRC)</td>
<td>ctDNA-guided therapy after surgery</td>
<td>• Undergone surgery for stage II/III colorectal cancer with available tissue &amp; whole blood samples • Using SIGNATERA test, may be recommended for adjuvant chemotherapy or observation by treating physician</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Dayyani</td>
<td>Krissy Ghio</td>
<td>UCI 20-43: Proof of Concept Study of ctDNA Guided Change in Treatment for Refractory Minimal Residual Disease in Colon Adenocarcinomas</td>
<td>ctDNA-guided change in adjuvant treatment</td>
<td>• 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</td>
<td>Pending activation</td>
</tr>
</tbody>
</table>

### Neoadjuvant Colorectal

- **PI:** Dr. Zell
  - **CRC:** Krissy Ghio
  - **Protocol No. and Title:** EA2182: A Randomized Phase II Study of De-Intensified Chemoradiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)
  - **Mechanism:** Standard dose vs de-intensified chemoradiation
  - **Primary Inclusion/Exclusion Criteria:**
    - Histologically proven T1-2N0M0 invasive anal canal or anal margin squamous cell carcinoma;
    - Tumors measuring < 4 cm within 4w prior to registration
  - **Status:** Open to accrual

- **PI:** Dr. Zell
  - **CRC:** Krissy Ghio
  - **Protocol No. and Title:** UCI 20-09: Short Course Radiation and TASOX (TAS102 plus Oxaliplatin) Chemotherapy in Operable Rectal Cancer, a Phase II Trial
  - **Mechanism:** Radiation + neoadjuvant TASOX, surgery
  - **Primary Inclusion/Exclusion Criteria:**
    - Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0
    - Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy
  - **Status:** Pending activation

### Metastatic Colorectal

#### Newly Diagnosed

- **PI:** Dr. Zell
  - **CRC:** Dorothy Chang
  - **Protocol No. and Title:** S0820: A Double Blind Placebo-Controlled Trial of Efornithine 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)
  - **Mechanism:** Ornithine decarboxylase (ODC) inhibitor + COX I/II inhibitor
  - **Primary Inclusion/Exclusion Criteria:**
    - 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)
  - **Status:** Open to accrual

- **PI:** Dr. Zell
  - **CRC:** Dorothy Chang
  - **Protocol No. and Title:** S0820: A Double Blind Placebo-Controlled Trial of Efornithine 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)
  - **Mechanism:** Ornithine decarboxylase (ODC) inhibitor + COX I/II inhibitor
  - **Primary Inclusion/Exclusion Criteria:**
    - 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)
  - **Status:** Open to accrual

- **PI:** Dr. Dayyani
  - **CRC:** Bao Huynh
  - **Protocol No. and Title:** UCI 20-03: BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer (CRC)
  - **Mechanism:** ctDNA-guided therapy after surgery
  - **Primary Inclusion/Exclusion Criteria:**
    - 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
  - **Status:** Open to accrual

- **PI:** Dr. Dayyani
  - **CRC:** Krissy Ghio
  - **Protocol No. and Title:** UCI 20-43: Proof of Concept Study of ctDNA Guided Change in Treatment for Refractory Minimal Residual Disease in Colon Adenocarcinomas
  - **Mechanism:** ctDNA-guided change in adjuvant treatment
  - **Primary Inclusion/Exclusion Criteria:**
    - 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
  - **Status:** Pending activation

- **PI:** Dr. FC Lee
  - **CRC:** Krissy Ghio
  - **Protocol No. and Title:** NRG-GI004: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer
  - **Mechanism:** anti-PO-L1 + anti-VEGF
  - **Primary Inclusion/Exclusion Criteria:**
    - 1st line treatment
    - Deficient MMR dMMR by IHC
  - **Status:** Open to accrual

- **PI:** Dr. Dayyani
  - **CRC:** Jasmine Balangue
  - **Protocol No. and Title:** UCI 20-46: Phase Ib Study of Gevokizumab in Combination with Standard of Care Anti-Cancer Therapies in Patients with Metastatic Colorectal Cancer, Gastroesophageal Cancer and Renal Cell Carcinoma
  - **Mechanism:** Gevokizumab in combo with FOLFIRI, FOLFOX6, Paclitaxel + Ramucirumab, and Cabozantinib
  - **Primary Inclusion/Exclusion Criteria:**
    - Histologically/cytologically confirmed metastatic disease not amenable to potentially curative surgery
    - Cohort A (1L mCRC): first line metastatic colorectal adenocarcinoma; prior systemic therapy, administered as radiosensitizer is allowed; prior adjuvant chemotherapy (if > 6 months prior to enrollment) is allowed
  - **Status:** Pending activation

### Contact Information:

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- **Cindy Dong:** 714-509-2740 | jdong@hs.ucr.edu
- **Dominique Viana:** 714-509-2720 | dotterta@hs.ucr.edu
- **Dorothy Chang:** 714-509-2139 | docorho@hs.ucr.edu
- **Jasmine Balangue:** 714-509-2948 | balangue@hs.ucr.edu
- **Krissy Ghio:** 714-456-6528 | kghio@hs.ucr.edu
- **Parvin Keshtmand:** 714-509-2739 | pkeshths@hs.ucr.edu

July 2021
## Metastatic Colorectal - Recurrent

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</table>
| Dr. Dayyani   | Krissy Ghio          | SWOG-S1613: A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in HER2 Amplified Irinotecan-Refractory Metastatic Colorectal Cancer (mCRC) | Trastuzumab, Pertuzumab vs Cetuximab and Irinotecan | • 2nd line treatment  
• Must have progressed on most recent systemic chemotherapy; irinotecan allowed  
• HER2 amplification (2+ or 3+ on IHC)  | Open to accrual |
| Dr. Dayyani   | Jasmine Balangue     | UCI 20-46: Phase II Study of Gevokizumab in Combination with Standard of Care Anti-Cancer Therapies in Patients with Metastatic Colorectal Cancer, Gastroesophageal Cancer and Renal Cell Carcinoma | Gevokizumab in combo with FOLFIRI, FOLFOX6, Paclitaxel + Ramucirumab, and Cabozantinib | • Histologically/cytologically confirmed metastatic disease not amenable to potentially curative surgery  
• Cohort B (2L mCRC): second line metastatic colorectal adenocarcinoma that has progressed on prior line of chemotherapy administered for metastatic disease, must include 5-FU and oxaliplatin | Pending activation |
| Dr. Dayyani   | Jasmine Balangue     | UCI 20-134: Phase I Study of Cabozantinib Plus TAS102 in mCRC as Salvage Therapy                           | Cabozantinib + TAS102            | • Histologically/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 | TBD                  | 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. | Pending activation |

## Intra-operative Colorectal

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</table>
| Dr. Carmichael | Jasmine Balangue     | UCI 20-163: Efficacy and Safety of the CG-100 Intraluminal Bypass Device in Colorectal and Colonoanal 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

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</table>
| Dr. Carmichael | Ana Gonzalez Vargas  | 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 |
# Gastrointestinal Clinical Trials

## Gastric and Gastroesophageal (GEJ)

### Gastric and GEJ - Newly Diagnosed

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<tr>
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<tbody>
<tr>
<td>Dr. Dayani</td>
<td>Cindy Duong</td>
<td>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</td>
<td>anti-CD39 + anti-PD-1 and/or mFOLOX6</td>
<td>• Cohort 3 (open): HER2-negative gastric adenocarcinoma, chemo-naïve (first line treatment)</td>
<td>Open to accrual</td>
</tr>
</tbody>
</table>
| Dr. Fachyi Lee | Dominique Vitanza | UCI 20-35: A Multicenter, Double-Blind, Randomized Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintiluzumab vs. Placebo, in Combination with Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15) | Sintiluzumab + Cisplatin + Paclitaxel or 5-FU | • Histopathologically confirmed unresectable, locally advanced, recurrent or metastatic ESCC  
• Must be unsuitable for definitive treatment (definitive chemo RT and/or surgery)  
• For subjects who have received (neo)adjuvant or definitive chemo/RT RT, time from completion of last treatment to disease recurrence must be >6 months | Open to accrual             |
| Dr. Dayani | Dominique Vitanza | UCI 20-63: A Phase IIa, Multicenter, Open-Label Study of DKN-01 in Combination with Tislezumab ± Chemotherapy as First-Line or Second-Line Therapy in Adult Patients with Inoperable, Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (DoTiShiGuish)  | DKN-01 + tislelizumab + CAPOX | • Part A will enroll G/GEJ adenocarcinoma patients who have received no prior systemic treatment in the locally advanced/metastatic setting (first-line treatment); exclusion: HER2-positive  
• Part B will enroll patients who received only 1 prior systemic treatment, which must consist of a platinum + fluoropyrimidine-base 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-B7: 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

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</table>
| Dr. Dayani | 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. Dayani | 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. Dayani | Jasmine Balangue | UCI 19-118: A Global Phase I Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of the Half-Life Extended Bispecific T-cell Engager AMG 910 in Subjects with 18.2-Positive Gastric and Gastroesophageal Junction Adenocarcinoma | AMG910 | • Positive for claudin 18.2  
• Refractory or relapsed after ≥2 lines of therapy  
• no prior treatment with any CLDN18.2-targeting product | Open to accrual             |
| Dr. Dayani | 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 IHC | Open to accrual (Part A only) |
| Dr. Dayani | Krissy Ghio   | ETCDN-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

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<tbody>
<tr>
<td>Dr. Carmichael</td>
<td>Carlos Chavez</td>
<td>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</td>
<td>TAK-954</td>
<td>• Scheduled to undergo laparoscopic-assisted or open partial small- or large-bowel resection</td>
<td>Open to accrual</td>
</tr>
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</table>
## Gastrointestinal Clinical Trials

### Liver

#### Early Stage HCC - Adjuvant

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</table>
| Dr. Dayyani | Dominique Vitanza | 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

<table>
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</table>
| Dr. Dayyani | Dominique Vitanza | UCI 19-37: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Transarterial Chemoembolization (TACE) in Combination with either Durvalumab Monotherapy or Durvalumab plus Bevacizumab Therapy in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-1) | TACE + anti-PD-L1 + anti-VEGF | • 1st line treatment  
• Imaging confirmed HCC  
• Child-Pugh A-B7  
• Vp1 and Vp2 portal vein thrombus allowed  
• Up to 4 TACE treatments allowed in 16-week period | Open to accrual |
| 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 (TACE) for Vascular Occlusion of Hypervascular Tumors; A Pivotal Study (INY-P-20-001) | Hydrogel embolic system vs SOC TACE/TACE | • Subjects must be > 22 years old  
• CT/MRI-confirmed hypervascular tumor where TAE/TACE 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 | Pending activation |
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</table>
| 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          |
| Dr. Abi-Jaoudeh     | Pam Singh      | UCI 16-94: Phase IIIA 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  | 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 | Multi-kinase 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          |

Contact Information:
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Jasmine Baluegu 714-509-2948 | baluegj@hsu.edu
Krissy Ghio 714-456-6258 | kghio@hsu.edu
Parvin Keshtmand 714-509-2739 | pkeshtma@hsu.edu

July 2021
## Gastrointestinal Clinical Trials

### Pancreas

#### Borderline Resectable or Locally Advanced Pancreatic

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</thead>
</table>
| Dr. Dayani | Kristy Ghio          | ECTTN-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 Electrom 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

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol No. and Title</th>
<th>Mechanism</th>
<th>Primary Inclusion/Exclusion Criteria</th>
<th>Status</th>
</tr>
</thead>
</table>
| Dr. Dayani | Dominique Vitanza    | UCI 19-120: An Open-Label, Randomised, Multicentre, Phase III Study of Irinotecan Liposome Injection, Oxaliplatin, 5-Fluorouracil/Leucovorin versus Nab-Paclitaxel Plus Gemcitabine in Subjects Who Have Not Previously Received Chemotherapy for Metastatic Adenocarcinoma of the Pancreas | Irinotecan liposome + oxaliplatin + 5-FU vs Gem + Abraxane                                           | • 1st line systemic treatment for metastatic pancreatic adenocarcinoma  
• Initial diagnosis of metastatic disease must have occurred < 6 weeks prior to screening | Open to accrual |
| Dr. Valerin | Jasmine Balangue     | E2A186: A Randomized Phase II Study of Gemcitabine and NabPaclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naive 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. Dayani | Cindy Duong          | UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budgalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors | anti-CD39 + anti-PD-1 + gem/abraxane                                                              | • Cohort 9 (open): Histologically or cytologically confirmed diagnosis of locally advanced, unresectable, or metastatic pancreatic adenocarcinoma  
• Naive to any prior treatment for metastatic disease (prior adjuvant therapy allowed if neoadjuvant/adjvant and if completed ≥ 6 months prior to enrollment)  
• Eligible to receive gemcitabine + nab-paclitaxel as standard of care | Open to accrual |
| Dr. Mar    | Dorothy Chang        | UCI 20-61: Phase 1/1b Study of the Safety of TTX-030 as a Single Agent and in Combination with Pembrolizumab or Chemotherapy in Patients with Lymphoma or Solid Tumor Malignancies | anti-CD39 + gem/abraxane                                                                            | • At least one tumor site (primary or metastasis) that is amenable to biopsy  
• Evidence of measurable disease by CT, PET-CT for dose escalation only, or MRI  
• Cohort 4 (Pancreatic): locally advanced, unresectable, or metastatic pancreatic adenocarcinoma; eligible to receive gemcitabine + nab-paclitaxel as standard of care  
• Treatment naive for metastatic disease. Prior adjuvant therapy is permitted if neoadjuvant or adjuvant therapy was completed ≥ 6 months prior to enrollment | Open to accrual |

#### Metastatic Pancreatic - Recurrent

<table>
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<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol No. and Title</th>
<th>Mechanism</th>
<th>Primary Inclusion/Exclusion Criteria</th>
<th>Status</th>
</tr>
</thead>
</table>
| Dr. Dayani | Jasmine Balangue     | ECTTN-1020B: A Phase I study of Anetumab Ravnatsine in Combination with either Anti-PD-1 Antibody, Anti-CTLA4 and Anti-PD-1 Antibodies or Anti-PD-1 Antibody and Gemcitabine in Mesothelin-Positive Advanced Pancreatic Adenocarcinoma | Anetumab Ravnatsine w/immunotherapy and gemcitabine                                               | • Positive for Mesothelin  
• Progressed or been intolerant to at least 1 systemic therapy | Open to accrual |

### Neuroendocrine

#### Poorly-differentiated Neuroendocrine Tumors

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<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol No. and Title</th>
<th>Mechanism</th>
<th>Primary Inclusion/Exclusion Criteria</th>
<th>Status</th>
</tr>
</thead>
</table>
| Dr. Dayani | Cindy Duong          | ECTTN-10315: A Phase II Study of XL184 (Cabozaatinib) in Combination with Nivolumab and Ipilimumab for the Treatment of Poorly Differentiated Neuroendocrine Carcinomas | Anti-PD-1 + anti-CTLA-4 + TKI                                                                | • 2nd line treatment - must have failed one prior line of systemic treatment  
• Metastatic, biopsy-proven poorly-differentiated neuroendocrine neoplasm per 2018 WHO classification (except small cell lung cancer and Merkel cell carcinoma)  
• Variations of poorly differentiated neuroendocrine carcinoma (e.g. small, large, and mixed cells) are eligible  
• Must have lesions suitable for pre-treatment and on-treatment biopsy  
• Stage 1 enrollment closed - currently pending analysis for Stage 2 recruitment | Suspended |
<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol No. and Title</th>
<th>Mechanism</th>
<th>Primary Inclusion/Exclusion Criteria</th>
<th>Status</th>
</tr>
</thead>
</table>
| 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 3 (open): HER2-negative gastric adenocarcinoma, chemo-naive (first line treatment)  
• Cohort 9 (open): Histologically 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 | 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 |
| Dr. Zhu | Keagan Buttigieg | UCI 19-57: Phase I, Open-Label, Multi-Center, First-In-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TTX-0022, A Novel Met/CSF1R/SRC Inhibitor, in Patients with Advanced Solid Tumors Harborhing 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 | Pending activation |
| Dr. Dayyani | Jasmine Balangue | UCI 20-46: Phase Ib Study of Gevokizumab in Combination with Standard of Care Anti-Cancer Therapies in Patients with Metastatic Colorectal Cancer, Gastroesophageal Cancer and Renal Cell Carcinoma | Gevokizumab in combo with FOLIRI, FOLFOX6, Paltitaxel + Ramucirumab, and Cabozantinib | • Histologically/cytologically confirmed metastatic disease not amenable to potentially curative surgery  
• Cohort A (1L mCRC): first line metastatic colorectal adenocarcinoma  
• Cohort B (2L mCRC): second line metastatic colorectal adenocarcinoma  
• Cohort C (2L mGEC): second line metastatic GEC adenocarcinoma  
• Cohort D (2/3L mRCC): second or third line metastatic renal cell carcinoma with a clear-cell component; has received one or two lines of treatment for metastatic disease | Suspended |
| Dr. Mar | Dorothy Chang | UCI 20-61: Phase I/ib Study of the Safety of TTX-030 as a Single Agent and in Combination with Pembrolizumab or Chemotherapy in Patients with Lymphoma or Solid Tumor Malignancies | TTX-030 (anti-CD39) | • Advanced solid tumor malignancy or relapsed/refractory lymphoma, or  
• Eligible to receive single-agent pembrolizumb or docetaxel as standard of care, or  
• Advanced pancreatic adenocarcinoma and eligible to receive gemcitabine+nab-paclitaxel as standard of care | Open to accrual |
| Dr. Valerin | Jasmine Balangue | UCI 20-67: A Phase I/I, 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 erb2-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 |
## Gastrointestinal Clinical Trials

### Advanced Solid Tumors

| Dr. Ou | Aranel Serwanska | UCI 20-68: A Phase II Study of Seribantumab (FTN100) in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors | Seribantumab (ERBB inhibitor) | • NRG1 gene fusion  
• 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 | Emiri Matsuda | UCI 20-127: A Phase III Randomized Placebo controlled Double-Blind Study of Romipiostim for the Treatment of Chemotherapy-Induced Thrombocytopenia in Patients Receiving Oxaliplatin-based Chemotherapy for Treatment of Gastrointestinal, Pancreatic, or Colorectal Cancer | Romipiostim/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 capcitabine 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 FOLOFOX, FOLFIRINOX, or FOLFOXIRI; 21 days removed if they received CAPEOX | Pending activation |
| Dr. Ou | Oliver Quines | UCI 20-185: A Phase I/II, 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 | • 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 IHC2+/HER2 non-amplified) gastric or GEJ cancer  
• Cohort D: HER2-expressing (IHC 3+ or 2+) or HER2-amplified NSCLC  
• Cohort E: Other HER2-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 IHC2+/HER2 amplified) breast cancer, gastrointestinal cancer  
• HER2-expressing (IHC 3+ or 2+) or HER2-amplified colorectal cancer, endometrial cancer, biliary tract cancer, cholangiocarcinoma, NSCLC, HNSCC, urothelial cancer | Pending activation |
| Dr. Ou | Oliver Quines | UCI 20-194: A Phase I/I, 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) | Pending activation |
| Dr. Ou | Keagan Buttigieg | 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 (SHP-2 inhibitor) | PF-07284892 (SHP-2 inhibitor) | • Histological or cytological diagnosis of ALK-positive advanced NSCLC, colorectal carcinoma with BRAF V600E mutation, or RAS-mutant, NF1-mutant or BRAF class 3-mutant solid tumor | Pending activation |
| Dr. Ou | Colin Pichon | UCI 21-12: A Phase I/II, 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) | Pending activation |
| Dr. Ou | TBD | UCI 21-55: A Phase Ib/II, Open-Label, Multi-Center Study of ERAS-007 ERK Inhibitor in Patients with Advanced or Metastatic Solid Tumors | ERAS-007 (ERK inhibitor) | • Histologically or cytologically confirmed advanced or metastatic solid tumor (Part A)  
• Part B or C, all groups, the relevant molecular alteration must be reported (e.g. solid tumors with mutation(s) in MAPK pathway: melanoma or NSCLC with BRAF V600 mutations; NSCLC with KRAS G12C alteration) | Pending activation |

### Other

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Jasmine Balexergue 714-509-2988 | balaxergue@hs.uci.edu  
Krisly Goh 714-456-6258 | kgoh@hs.ucla.edu  
Parvin Keshtmand 714-509-2739 | pkeshhtma@hs.ucla.edu | 8 | July 2021 |
<table>
<thead>
<tr>
<th>Advanced Solid Tumors</th>
<th>Dose Escalation Phase:</th>
<th>Dose Expansion Phase:</th>
</tr>
</thead>
</table>
| **Dr. Ou**  
Oliver Quines  
714-456-6244  
UCI 21-32: A Phase I Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Doses of PF-06939999 (PRMT5 Inhibitor) in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer, Head and Neck Squamous Cell Carcinoma, Esophageal Cancer, Endometrial Cancer, Cervical Cancer and Bladder  
PF-06939999 (PRMT5 Inhibitor)  
• Histological or cytological diagnosis of a solid tumor that is advanced/metastatic for the following tumor types: NSCLC, HNSCC, esophageal, endometrial, cervical, bladder  
• Participants must be intolerant to standard treatment or resistant to standard therapy (intolerance or progression must be documented) | Pending activation |
| **Dr. Valerin**  
Parvin Keshtmand  
UCI 21-40: A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications  
DF6002 and/or nivolumab  
• Histologically or cytologically proven locally advanced or metastatic solid tumors, for which no standard therapy exists or standard therapy has failed: melanoma, NSCLC, small cell lung, HNSCC, urothelial, gastric, esophageal, cervical, HCC, Merkel cell, cutaneous squamous cell carcinoma, RCC, endometrial, TNBC, ovarian, and prostate | Pending activation |
| **Dr. Rezazadeh**  
TBD  
UCI 20-179: A Phase I/II First-in-Human Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Patients with Advanced Solid Tumors  
SHP2 inhibitor  
• Diagnosis of advanced (primary or recurrent) or metastatic solid tumor with MAPK-pathway alterations (excluding BRAF V600X)  
• 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 |
| **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  
• Stage 1 and 2: Histologically or cytologically confirmed advanced/metastatic extracranial solid tumor malignancy  
• Subject must have received, have been intolerant to, have been ineligible for, or have declined all treatment known to confer clinical benefit (exception: subjects enrolled in combination cohorts with pembrolizumab in settings where pembrolizumab is approved)  
• Evaluable/measurable disease per RECIST v1.1, that has objectively progressed since (or on) previous treatment per treating investigator  
• Exclusion: prior JTX-8064, LILRB2, or ILT4-directed therapies | Pending activation |

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Parvin Keshtmand 714-509-2739 | pkeshtma@hs.ucr.edu
### Gastrointestinal Clinical Trials

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<tr>
<th>PI</th>
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</thead>
<tbody>
<tr>
<td>Dr. O’Brien</td>
<td>Carmen Lam</td>
<td>NCICOV1D: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study</td>
<td>Data, specimen, and image collection</td>
<td>• 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 &lt; 14 days</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Imagawa</td>
<td>Chang Shim</td>
<td>UCI 03-03: Immunologic Factors Affecting Outcomes in Patients with Liver Cancer</td>
<td>Immunologic response analysis</td>
<td>• Primary or metastatic liver cancer, scheduled for surgery with Dr. Imagawa or Dr. Demirjian</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Jutric</td>
<td>Chang Shim</td>
<td>UCI 08-70: Establishment of a multidisciplinary pancreatic tumor biorepository and integrated clinical database</td>
<td>Biobank</td>
<td>• Pancreatic lesion suspicious of cancer</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Zell</td>
<td>Chang Shim</td>
<td>UCI 15-20: A Pilot Study to Establish Proof-of-Concept that Patient-Specific Tumor Tissue Can Be Maintained in the Novel Tumor-on-a-Chip Model</td>
<td>Tumor-on-a-chip technology</td>
<td>• Known or suspected diagnosis of rectal cancer, planning to undergo endoscopy</td>
<td>Suspended</td>
</tr>
<tr>
<td>Dr. Bristow</td>
<td>Ashley Chanthapadith</td>
<td>UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California</td>
<td>Health services research</td>
<td>• Adults diagnosed with colorectal, liver, stomach cancer</td>
<td>Pending activation</td>
</tr>
<tr>
<td>Dr. Dayyani</td>
<td>Jasmine Balangue</td>
<td>UCI 19-55: A Non-Interventional Biomarker Study on the Molecular Evaluation of Archival Tumor Tissue in Subjects with Gastric Cancer</td>
<td>MUC17 and CLDN18.2 tissue testing</td>
<td>• 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</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Waterman</td>
<td>Chang Shim</td>
<td>UCI 20-04: University of California Minority Patient-Derived Xenograft (PDX) Development and Trial Center (UCaMP) to Reduce Cancer Health Disparities</td>
<td>Tissue collection</td>
<td>• Patient receiving treatment for the above 4 cancers (bladder cancer, lung cancer, gastric/stomach cancer, and liver cancer)</td>
<td>Open to accrual</td>
</tr>
<tr>
<td>Dr. Safari</td>
<td>TBD</td>
<td>UCI 20-64: Assessing the Effects of High-Fructose Corn Syrup on Human Colorectal Tumors</td>
<td>Blood collection pre- and during surgery, biochemical assays</td>
<td></td>
<td>Pending activation</td>
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<tr>
<td>Dr. Senthil</td>
<td>Krissy Ghio</td>
<td>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</td>
<td>Biospecimen collection for patients planned to start treatment</td>
<td>• Must have immunotherapy-naive histologically, radiologically, or cytologically confirmed cancer (e.g. melanoma, HCC, colorectal, appendix or gastric cancer) • Must have measurable disease at time of enrollment</td>
<td>Open to accrual</td>
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