UCI Chao Family Comprehensive Cancer Center

Breast Oncology					
MD	**CRC**	**Study Title**	**Mech of Action**	**Broad Eligibility**	**Study Status**
Dr. Parajuli	Alexis Chavez	ETCTN 10546 Phase I TNBC Targeting DNA Methyltransferases in Metastatic Triple-Negative Breast Cancer	Cytidine deaminase (CDA) inhibitor + nucleoside hypomethylating agent (HMA)	Inclusion: Patients must have histologically confirmed TNBC Patients with treated brain metastases are eligible if there is evidence of measurable extracranial disease, and if follow-up brain imaging 4 weeks after central nervous system (CNS)-direct therapy shows no evidence of progression. Any number of prior lines in the metastatic setting. Exclusion: Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy Has a known additional malignancy that is progressing or requires active treatment.	Suspended
Dr. Parajuli	Juan Miranda	UCI 22-09 A Phase Ib, First-In-Human, Dose Escalation and Expansion, Multicenter Study of XMT-1660 in Participants with Solid Tumors	Antibody drug conjugate	Inclusion: Proven recurrent or advanced solid tumor and has disease progression after treatment with available anti-cancer therapies TNBC inclusion: DES and Backfill Cohorts: Participant has received at least 2 lines of systemic therapy in a locally advanced or metastatic BC setting. EXP: Participant has received 1 to 3 prior lines of chemotherapy in a locally advanced or metastatic BC setting. HR+, HER2- inclusion: DES and Backfill Cohorts: Participant has received at least 1 line of systemic therapy, which must have included a CDK4/6 inhibitor(s) and ET in an advanced or metastatic BC setting. EXP: Participant must have received prior therapy with a CDK4/6 inhibitor(s) combined with ET in any setting Exclusion: Participant has received prior treatment with another ADC containing an auristatin or maytansinoid payload Participant has had major surgery within 28 days of starting study treatment; systemic anti-cancer therapy within the time period of 28 days or 5 half-lives of the prior therapy before starting study treatment (14 days or 5 half-lives for small molecule targeted therapy), whichever is less; or palliative radiation therapy within 14 days of starting study treatment.	Open to Accrual

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Dr. Parajuli	Juan Miranda	UCI 22-156 A Phase Ib Study of TBio-4101 (Autologous Selected and Expanded Tumor-Infiltrating Lymphocytes [TIL]) and Pembrolizumab in Patients with Advanced Solid Tumor Malignancies (STARLING)	Tumor infiltrating lymphocyte therapy	Inclusion: Patients with breast cancer must have relapsed on at least one and no more than three prior treatments for metastatic disease (adjuvant/neoadjuvant therapy will not count toward the three prior therapies limit.) Patients with HER2-positive disease must have received a HER2-containing regimen. Patients with BRCA mutations must have previously been treated with a targeted therapy. Exclusion: Patients with known active central nervous system (CNS) metastases (Patients with previously treated brain metastases may participate provided they are radiologically stable) Patients with a known additional malignancy that is progressing or has required active treatment within the past 3 years.	Open to Accrual
Gastrointestinal Oncology					
Dr. Lee	Nicole Ferrand	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	BXQ-350 + mFOLFOX7 and bevacizumab	Inclusion: • Must have measurable disease Exclusion: • Cannot have confirmed dMMR or MSI-H • Cannot have Type 1 or 2 diabetes mellitus	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 • 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	Open to Accrual

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Dr. Dayyani	Jensen Koff	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	FGFR inhibitor + mFOLFOX6 + antiPD-L1 (nivolumab)	• Histologically documented gastric or gastroesophageal junction adenocarcinoma • Previously treated disease that is unresectable, locally advanced, or metastatic; perioperative therapy is allowed if < 6 months • Measurable disease or non-measurable, but evaluable disease, per RECIST v1.1 • FGFR2b overexpression as determined by central testing	Open to Accrual
Dr. Dayyani	Peter Yang	UCI 22-221 A First-in-human Phase I, Non-randomized, Open-label, Multi-center Dose Escalation Trial of Bi 765049 and Bi 765049 + Ezabenlimab Administered by Repeated Intravenous Infusions in Patients with Malignant Solid Tumors Expressing B7 H6	(Central B7-H6 testing) HCC and Pancreatic (also NSCLC, HNSCC, CRC, and gastric)	CRC patients do not require prescreening consent	Open to Accrual
Dr. Dayyani	My Ha Nguyen	ETCTN 10495 Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations	DS-8201a + Neratinib	Inclusion: • Patients must have HER2-positive as determined by any one or more of the following: ▣ HER2-overexpressing defined by IHC 3+ ▣ ERBB2 amplification by ISH or next generation sequencing as determined by any CLIA certified lab ▣ A known HER2 activation mutation • Patients must have received at least 1 prior line of therapy in the advanced/metastatic setting. No limitation on number of prior therapies Exclusion: • Prior treatment with neratinib or DS-8201a	Open to Accrual

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Dr. Dayyani	My Ha Nguyen	ETCTN 10358 Phase I/IB Study of DS-8201a in Combination with ATR Inhibition (AZD6738) in Advanced Solid Tumors with HER2 Expression (DASH Trial)	DS8201a + AZD6738	• Patients must have HER2-positive or HER2-expressing tumors determined by a CLIA-certified laboratory ◘ HER2 expression (1-3+) by IHC locally and confirmed centrally OR ◘ HER2 expression (1-3+) by IHC tested centrally OR ◘ HER2 amplification based on FISH or Next Generation Sequencing • Must have received at least one line of systemic chemotherapy for either locally advanced or metastatic disease and should have either progressed on this therapy or been intolerant to this therapy • For tumors where anti-HER2 therapy is standard of care, patients must have progressed on at least 1 line of anti-HER2 therapy if eligible. For patients where DS8201a is approved as standard of care, prior treatment with DS8201a is not allowed • Dose-escalation phase: Must have histologically confirmed advanced solid tumor including but not restricted to breast cancer, gastric or gastroesophageal cancer, colon cancer, endometrial cancer, salivary gland tumors, and hepatobiliary tumors • Dose-expansion phase: Must have histologically confirmed advanced/metastatic gastroesophageal cancer (cohort A) or colorectal cancer (cohort B)	Open to Accrual
Dr. Lee	Peter Yang	ETCTN 10579 Phase I Trial of ZEN003694 (ZEN-3694) in Combination with Capecitabine in Patients with Solid Tumors	ZEN003694 (ZEN-3694) + capecitabine	<u>Dose Escalation additional criteria:</u> Patients must have histologically confirmed cancer that is metastatic or unresectable and must have progressed on standard therapies whichwould have included 5-FU or capecitabine <u>Dose Expansion additional criteria:</u> Patients must have histologically confirmed CRC that is metastatic or unresectable and must have progressed on standard therapies which would have included 5-FU or capecitabine *pre and post treatment biopsies are required for specific cohorts	Open to Accrual
Dr. Valerin	TBD	UCI 21-67 Phase I Study of Epacadostat Added to Preoperative Chemoradiation in Patients with Locally Advanced Rectal Cancer	Epacadostat + short course radiation + chemo	• Plans to proceed with neoadjuvant short course radiation and chemotherapy • No prior anti-cancer therapy for rectal cancer	Pending Activation

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Dr. Dayyani	Nicole Ferrand	UCI 22-51 A Phase I/Ib Study of ASP2138 in Participants with Metastatic or Locally Advanced Unresectable Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma or Metastatic Pancreatic Adenocarcinoma Whose Tumors Have Claudin (CLDN) 18.2 Expression	ASP2138	Inclusion: • Positive for CLDN 18.2 by central IHC testing • Participant with gastric or GEJ adenocarcinoma who has progressed, is intolerant, has refused, or for whom there is no standard approved therapies that impart significant clinical benefit based on investigator's clinical judgment • Participant with pancreatic adenocarcinoma who has progressed, is intolerant, has refused, or for whom there is no standard approved therapies that impart significant clinical benefit based on investigator's clinical judgment Exclusion: • Participant who has received an CLDN18.2-targeted investigational agent (e.g., zolbetuximab or chimeric antigen receptor CLDN18.2-specific T cells) prior to first dose of study intervention administration is not eligible for dose escalation cohorts	Open to Accrual
Dr. Dayyani	My Ha Nguyen	UCI 23-109 A Phase Ib/II Open-Label Study of Disitamab Vedotin Monotherapy or in Combination with Other Anticancer Therapies in Solid Tumors	Disitamab Vedotin + Tucatinib	Escalation phase: Previously treated advanced GC/GEJC or Breast Cancer (HER2-expressing) Expansion phase: Expansion Phase Cohort B HER2+ 3L or higher Breast Cancer, HER2-low 2L GC/GEJC	Open to Accrual
Dr. Dayyani	Krissy Ghio/ Jensen Koff	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.	Open to Accrual
Genitourinary Oncology					

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Dr. Rezazadeh	Jorge Loaiza	UCI 22-129 A Phase I/II Randomized, Umbrella Study to Evaluate the Safety and Efficacy of Pembrolizumab Plus Enfortumab Vedotin (EV) in Combination With Investigational Agents Versus Pembrolizumab Plus EV, as First-Line Treatment for Participants With Advanced Urothelial Carcinoma (KEYMAKER-U04): Substudy 04B	Part 1 (safety lead-in) Arm A: EV IV + MK-4280A IV Arm B: EV IV + MK-7684A IV Arm C: EV IV + Pembro IV	*Previously untreated LA/mUC; select prior therapy for MIUC permitted *Archival or new tumor *No restriction regarding PD-L1 CPS	Suspended
Dr. Mar	Ariana Castro	GOG-3082 A Phase Ib/II Basket Study of ACR-368 as Monotherapy and in Combination with Gemcitabine in Adult Subjects with Platinum-Resistant Ovarian Carcinoma, Endometrial Adenocarcinoma, and Urothelial Carcinoma Based on Acrivon OncoSignature® Status	Arm 1: OncoSignature (+): ACR-368 IV Arm 2: OncoSignature (-): ULDG IV + ACR-368 IV	*Ovarian: PD/relapse ≤ 6 months of platinum therapy completion; 1-6 lines of prior therapy *Endometrial: ≤ 3 lines of prior therapy in recurrent setting; failed/ineligible for PD(L)-1 for adv/met disease *UC: received platinum; failed PD(L)-1/EV; if in neo/adjuvant setting, progression ≤ 12 months*Must undergo new tumor biopsy from accessible tumor lesion	Open to Accrual
Dr. Rezazadeh	Jorge Loaiza	UCI 22-128 A Phase I/II Open-Label Rolling-Arm Umbrella Platform Study of Investigational Agents With or Without Pembrolizumab in Participants with PD-1/L1 Refractory Locally Advanced or Metastatic Urothelial Carcinoma (KEYMAKER-U04): Substudy 04A	MK-2140 (Zilovertamab Vedotin) IV D1/D8 Q3W	*PD(L)-1 refractory LA/mUC with progression during/after treatment *PD(L)-1 monotherapy refractory MIUC with recurrence while on treatment or ≤ 6 months of treatment completion *Archival or new MIUC or metastatic tissue	Suspended

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Dr. Mar	Amanda Macaraeg	ETCTN 10301 A Phase I and Randomized Phase II Trial of Radium-223 Dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC)	A: 223Ra (bone-targeted alpha particle emitting radiopharmaceutical) IV x6 B: 223Ra IV x6 + M3814 (DNA-PK inhibitor) PO BID C: 223Ra IV x6 + avelumab (anti-PD-L1 IgG1 Ab) IV x10 + M3814 PO BID	*Progressive mCRPC with ≥ 2 skeletal mets via bone scan with LN mets < 3cm in long axis and no visceral organ mets *Progression after at least one of the following: abi, enza, apalutamide, darolutamide, or taxane chemo *On ADT unless had orchiectomy	Open to Accrual
Dr. Rezazadeh	Ali Raad	UCI 23-162 A First-in-human, Phase I/II, Open-label, Multi-center, Dose-Escalation, Dose-optimization, and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Anti-tumor Activity of PARP1 Selective Inhibitor, IMP1734, in Patients with Advanced Solid Tumors	IMP1734 oral	*Ongoing ADT within 28d of study entry, must have received NHA, must have received 1 prior line of taxane-based chemotherapy *BRCA1/2, PALB2, RAD51B/C/D mutation required	Open To Accrual
Gynecologic Oncology					

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Dr. Tewari	Jiana Ejbara	UCI 22-42 Phase I/II, Open-label Dose Escalation and Dose Expansion Study of TransCon TLR7/8 Agonist, Alone or in Combination with Pembrolizumab in Participants with Locally Advanced or Metastatic Solid Tumor Malignancies	TransCon Toll like receptor (TLR) 7/8 agonist	• Participants must have histologically confirmed locally advanced, recurrent or metastatic solid tumor malignancies that cannot be treated with curative intent (surgery or radiotherapy). - Patients in neoadjuvant cohorts are exempt. • At least 2 lesions of measurable disease per RECIST 1.1, unless specified otherwise in the selection criteria – at least 1 lesion that is safely accessible for intratumoral injection and 1 lesion that is not injected (at least initially). • Lesion(s) to be injected must be measurable and greater than or equal to 15 mm in the longest diameter at initial selection. Exclusion: Participants who have been previously treated with a TLR agonist (excluding topical agents for unrelated disease) are not eligible. Other active malignancies within the last 2 years are excluded. Known hypersensitivity to any component of TransCon TLR7/8 Agonist or pembrolizumab.	Open to Accrual
Dr. Tewari	Jiana Ejbara	UCI 22-77 Phase I First-in-Human Study to Explore the Safety, Tolerability and Pharmacokinetics of AMG 794 in Subjects with Claudin 6-Positive Advanced/Metastatic Non-Squamous Non-Small Cell Lung Cancer or Epithelial Ovarian Cancer and Other Malignant Solid Tumor Indications	AMG794 half-life extended (HLE) BiTE molecule targeting CLDN6	Inclusion: • Subjects with histologically or cytologically documented malignant solid tumor diseases expressing CLDN6 including but not limited to NSCLC, EOC, testicular germ cell cancer, uterine endometrial cancer, or triple negative breast cancer, that is metastatic or unresectable at screening time point. Subjects should have exhausted available SOC systemic therapy or should not be candidates for such available therapy. • For dose expansion cohorts: Subjects with at least 1 measurable lesion ≥ 10 mm which has not undergone biopsy within 3 months of screening scan. This lesion cannot be biopsied at any time during the study. Exclusion: • History of other malignancy within the past 2 years, with the following exceptions: - Malignancy treated with curative intent and with no known active disease present for ≥ 2 years before enrollment and understood to be at low risk for recurrence by the treating physician. - Adequately treated cervical carcinoma in situ without evidence of disease. - Adequately treated breast ductal carcinoma in situ without evidence of disease.	Suspended

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Dr. Tewari	Jiana Ejbara	UCI 22-78 A Phase I Study of KSQ-4279 Alone and in Combination in Patients with Advanced Solid Tumors	KSQ-4279 +/- Olaparib or Carboplatin Targeting deleterious mutation (germline or somatic)	Inclusion: Deleterious mutation (germline or somatic) in at least 1 of the following genes involved in the HRR pathway Histologically diagnosed recurrent or persistent high grade serous ovarian cancer (including primary peritoneal and/or fallopian tube cancer) Received prior platinum-based chemotherapy Patients may have platinum-sensitive or resistant disease Exclusion: Ongoing Grade 2 or greater toxicity, except alopecia, related to any prior treatment (ie, chemotherapy, targeted therapy, radiation, or surgery). Chemotherapy or small molecule-targeted therapy < 2 weeks prior to first dose of study treatment. Known hypersensitivity to study therapies and its excipients.	Open to Accrual
Hepatobiliary and Pancreas Oncology					
Dr. Dayyani	Han Nguyen	UCI 22-106 A Phase IB/II Multicenter, Open-Label Study to Evaluate the Safety and Efficacy of TTI-101 as Monotherapy and in Combination in Participants with Locally Advanced or Metastatic, and Unresectable Hepatocellular Carcinoma	STAT3 ± Pembrolizumab or ± Atezolizumab and Bevacizumab	• Locally advanced, metastatic, and unresectable HCC • Cohort A, monotherapy: must have progressed on up to 3 prior lines of systemic therapy • Cohort B, pembro: no more than 1L of therapy and must have progressed after at least 3 months of anti-PD(L)1 therapy • Cohort C, atezo + bev: must be treatment naive to systemic therapy for advanced, mets, or unresectable disease • Cohorts A + B: biopsy required	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	MRG004A (TF ADC)	• 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 central IHC	Open to Accrual

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Dr. Dayyani	Jasmine Balangue	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	CB-03-10 (Androgen and glucocorticoid antagonist)	• Part 1 (Dose Escalation): histologically or cytologically confirmed relapsed or refractory advanced or metastatic solid tumor of any origin, not amenable to standard of care therapy • Measurable or evaluable disease per RECIST v1.1 criteria	Open to Accrual
Dr. Abi	TBD	UCI 23-24 A Phase 1b/2 Pressure Enabled Regional Immuno-Oncology Study of Hepatic Arterial Infusion of SD-101 with Systemic Checkpoint Blockade for Hepatocellular Carcinoma and Intrahepatic Cholangiocarcinoma	HAI SD-101+Pembro or Nivo	• Locally advanced, metastatic, or unresectable HCC or liver-dominant intrahepatic cholangiocarcinoma • Previously received 1L of therapy for liver cancer w/persistent or progressive measurable disease per RECIST 1.1	Pending Activation
Dr. Dayyani	Han Nguyen	ETCTN 10522 A Phase I Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma	CA4948 + gemcitabine + nabpaclitaxel	• Histologically or cytologically confirmed adenocarcinoma of the pancrease that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective • Disease progression on or after 5-FU-based therapy for metastatic or unresectable PDAC. Prior use of gemcitabine/nab-paclitaxel for metastatic or unresectable disease is not allowed	Suspended
Dr. Valerin	TBD	UCI 23-85 An Open-Label, Multicenter, Phase I Study Evaluating the Safety, Pharmacokinetics, and Efficacy of BA3182, A Bispecific Epithelial Cell Adhesion Molecule (EPCAM)/CD3 Antibody, in Patients with Advanced Adenocarcinoma	BA3182 (CAB T-cell: EpCAM)	Locally advanced unresectable or metastatic adenocarcinoma for which SOC has failed, or no curative therapy is available, or are not eligible, intolerant Part 1: Archived tumor tissue or tissue amenable to biopsy for central EpCAM testing (no samples older than 12 months) (positivity not required) Part 2: must have EpCAM central positive disease (3 cores mandatory)	Pending Activation

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Dr. Valerin	Han Nguyen	ETCTN 10464 A Phase I Study of Olaparib in Combination with Durvalumab (MEDI4736) and Concurrent Radiation Therapy Following First-Line Chemotherapy in Locally Advanced Unresectable Pancreatic Cancer	Olaparib with Durvalumab + radiation therapy	• Locally advanced pancreatic adenocarcinoma as determined by tumor board or surgically determined failed resection attempt • Received at least 16 weeks of any chemotherapy without progression	Open to Accrual
Dr. Dayyani	Nicole Ferrand	UCI 23-215 A Phase I/II Open-Label Study to Evaluate the Safety, Cellular Kinetics and Efficacy of AZD5851, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against GPC3 in Adult Participants With Advanced/Recurrent Hepatocellular Carcinoma: ATHENA	AZD5851 (GPC3 Autologous CAR-T)	Confirmed advanced/recurrent or metastatic and/or unresectable HCC based on histopathological findings - Received at least one prior line of standard systemic therapy, and for which a clinical study is the best option for the next treatment based on prior response and/or tolerability and/or participant/investigator decision - 1 measurable lesion per RECIST 1.1 - F38CPA prior to apheresis	Pending Activation
Malignant Heme Oncology					
Dr. O'Brien	Stephanie Osorio	UCI 20-198 A Phase I, Dose Escalation, Safety and Tolerability Study of NX-2127, a Bruton's Tyrosine Kinase (BTK) Degrader, in Adults with Relapsed/Refractory B-cell Malignancies	NX-2127, Bruton's tyrosine kinase degrader, in adults w/ R/R B-cell malignancies	Inclusion: Received at least 2 prior lines of therapy Histologically confirmed R/R CLL, SLL, WM, MCL, MZL, FL (grade 1-3b), and DLBCL e/ MYC & BCL2 and/or BCL6 rearrangements and high-grade B-cell lymphoma NOS	Suspended
Dr. Naqvi	Stephanie Osorio	UCI 21-239 An Open-Label, Phase IB Study of R289, an IRAK1/4 Inhibitor, in Patients with Lower-Risk Myelodysplastic Syndrome (LR MDS) Who are Refractory/Resistant to Prior Therapies	IRAK 1/4 inhibitor, R289, in patients w/ refractory or resistant lower-risk MDS	Inclusion: relapsed, refractory/resistant or inadequate response to all therapies with now clinical benefits, such as TPOs, EPOs, lupatercept and HMAs for MDS. Meet at least one dx-related criteria for RBC transfusion, plt count or ANC <8W prior to study tx initiation. Received at least one line of therapy	Open to Accrual

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Dr. Jeyakumar	Stephanie Osorio	UCI 22-151 A Phase I, Open-Label, Multi-Center Study of the Safety, Pharmacokinetics (PK), and Anti-Tumor Activity of LYT-200 in Patients with Relapsed/Refractory Acute Myeloid Leukemia (AML), or with Relapsed/Refractory, High-Risk Myelodysplastic Syndrome (MDS)	LYT-200 in patients w/ R/R AML or high-risk MDS	Inclusion: Confirmed dx of relapsed/refractory AML or MDS Exclusion: Must not be diagnosed w/ APL or has undergone HSCT <6 month prior to first study dose	Open to Accrual
Dr. Jeyakumar	Stephanie Osorio	UCI 19-138 A Phase Ib/II Study of IMGN632 as Monotherapy or Combination with Venetoclax and/or Azacitidine for Patients with CD123-Positive Acute Myeloid Leukemia	IMGN632 as monotherapy or combination w/ Venetoclax and/or Azacitidine for patients w/ CD123-positive AML	Inclusion: Confirmed dx of XD123+ AML	Suspended
Dr. Jeyakumar	Stephanie Osorio	UCI 22-81 A Phase I/II, Open-Label, Multicenter, Dose Escalation and Expansion Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HM43239 in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML)	HM43239 in patients w/ R/R AML	Inclusion: morphologically documented primary/secondary AML. R/R at least one cycle of prior therapy or the most recent therapy.	Open to Accrual

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Dr. Jeyakumar	Judit Castellanos	UCI 22-24 A Phase I First-in-Human Dose-Escalation and Dose-Escalation and Dose-Expansion Study of BMF-219, an Oral, Covalent, Menin Inhibitor, in Adult Patients with Acute Leukemia (AL), Diffuse Large B-Cell Lymphoma (DLBCL), Multiple Myeloma (MM), and Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	BMF-219 in patients w/ AL, DLBCL, MM, CLL/SLL	Inclusion: R/R AML w/ failure of SOC therapies. R/R DLBCL received at least 2 previous systemic regimens R/R MM received at east 3 regimens R/R CLL/SLL received at least 2 prior systemic regimens Exclusion CNS involvement Prior menin inhibitor therapy	Suspended
Dr. O'Brien	Emiri Matsuda	UCI 20-126 A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ANTLER)	CB-010, CRISPR-edited allogeneic anti-CD10 CAR-T cell therapy	Inclusion: Histologically confirmed aggressive B-NHL of one of the following types: For Part A: DLBCL NOS, HGBL, tFL, PMBCL, FL, MZL and MCL; For Part B: DLBCL NOS, HGBL, tFL, and PMBCL. Must have documented CD19+ disease and underwent adequate prior chemotherapy. Must not have history of prior therapy with an anti-CD19 targeting agent (Part A only)	Open to Accrual
Dr. Coombs	Emiri Matsuda	UCI 22-134 A Phase IB Study of Oral AS-1763 in Patients With Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma or Non-Hodgkin Lymphoma	Oral AS-1763 in patients w/ previously treated CLL/SLL or NHL	Inclusion - histologically confirmed B-cell malignancy (CLL/LL, WM, MCL, MZL, or FL) meeting the criteria for systemic treatment - at least 1 radiographically measurable lesion for SLL, MCL, MZL, or FL - failed at least 2 lines of prior systemic therapy Exclusion - Richter's transformation prior to or during screening - prior auto/allo transplant or CAR-T <30 days	Open to Accrual

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Dr. Pinter-Brown	Regan Dagenhart	UCI 21-225 A Phase IB, Open-Label, Multicenter, Single Arm Study Evaluating the Preliminary Efficacy, Safety, and Pharmacokinectics of Glofitamab in Combination with Rituximab Plus Ifosfamide, Carboplatin Etoposide Phosphate in Patients with Relapsed/Refractory Transplant Eligible Diffuse B-Cell Lymphoma	Glofitamab+ R-ICE in patients w/ R/R transplant eligible DLBCL	Inclusion: Histologically confirmed B-cell lymphoma (DLBCL-NOS, including EBV+ DLBCL, HGBCL w/ MYC and B-cell lymphoma 2 and/or B-cell lymphoma 6 rearrangements, HGBCL- NOS. Treated w/ 1 line of prior systemic therapy, including an anti-C20 monoclonal antibody and an anthracycline. R/R after 1st line chemoimmunotherapy. Candidate for high-dose chemotherapy followed by ASCT or CAR-T. At least one bi-dimensionally measurable nodal lesion (>1.5cm) or one bi-dimensionally measurable □ 1 cm) extranodal lesion, as measured on CT.	Suspended
Dr. Pinter-Brown	Regan Dagenhart	UCI 21-99 An Open-Label, Multi-Center, Non Randomized Phase I Dose-Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of ONO-4685 Given as Monotherapy in Patients with Relapsed or Refractory T-Cell Lymphoma	ONO-4685 given as monotherapy	Inclusion: Histologically or cytologically confirmed diagnosis of one of the following subtypes of T-cell lymphoma: AITL, PTCL-NOS, nodal PTCL with TFH, FTCL, MF, or SS. At least 2 prior systemic therapies. Eligible for CD30-directed therapy (e.g. bretuximab vedotin). Exclusion: CNS involvement, ATLL	Open to Accrual
Dr. Naqvi	Stephanie Osorio	UCI 23-154 Phase I Study to Determine the Safety and Tolerability of Ziftomenib Combinations for the Treatment of KMT2A-Rearranged or NPM1-Mutant Relapsed/Refractory Acute Myeloid Leukemia	Ziftomenib combinations for the KMT2A-rearranged/NPM1 mutant R/R AML	Inclusion - >18-75y/o, AML diagnosis per WHO - R/R to at least 1 prior line of therapy (R/R: ≥5% blasts in the BM or reappearance of blasts in the blood in ≥2 peripheral blood samples ≥1 week apart; or development of new extramedullary disease. - documented NPM1 mutation or KMT2Arearrangement	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Naqvi	Judit Castellanos	UCI 24-48 Phase I/II Study of DFP-10917 in Combination with Venetoclax in Relapsed or Refractory Acute Myeloid Leukemia	DFP-10917+Venetoclax in R/R AML	Inclusion - Histologically or pathologically confirmed diagnosis of AML based on WHO classification that has relapsed after, or is refractory to, up to 2 prior induction regimens that may have included intensive chemotherapy, epigenetic therapy, or targeted therapy * Relapse: ≥5% leukemia blasts in bone marrow or ≥1% blasts in peripheral blood 90 days to 24 months after first CR/CRi * Refractory: persistent disease ≥28 days after initiation of intensive induction therapy (up to 2 induction cycles) or relapse < 90 days after first CR/Cri Projected life expectancy of ≥12 weeks Female w/ childbearing potential a. Have a negative serum or urine pregnancy test prior to study treatment initiation. b. Agree to use at least 1 highly effective form of contraception during study treatment and for 3 months after the last dose. Male w/ childbearing potential: Agree to use at least 1 highly effective form of contraception during study treatment and for at least 3 months after the last dose Exclusion - Leukemic blast count >25 × 109 /L. Hydroxyurea permitted to control leukocytosis Venetoclax exposure in more than 1 prior regimen Prior HSCT	Pending Activation
Dr. Ciurea	Judit Castellanos	UCI 24-02 Descartes-15 for Patients with Relapsed/Refractory Multiple Myeloma	Descartes-15 in R/R MM	Failure of at least 3 prior lines of therapy which must have included an immunomodulatory drug, a protease inhibitor, and an anti-CD38 drug or biologic Measurable myeloma must be >100 days post-transplant at the time of leukapheresis	Pending Activation
Dr. Lee	Stephanie Osorio	UCI 23-225 A Phase I Trial of Selinexor, Ruxolitinib and Methylprednisolone for Patients with Relapsed/Refractory Multiple Myeloma	Selinexor, Ruxolitinib and Methylprednisone in R/R MM	Inclusion - confirmed diagnosis per standard criteria At lease 3 lines of prior therapies, including anti-CD38, IMiD, and PI Measurable disease/progressive MM Prior adminstration of growth factor support must have 2-week interval between last administration and the screening assessments. But growth factor support is allowed during the study	Pending Activation
Neuro Oncology					

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Bota	Hanh Ngo	UCI 23-67 A Phase Ib Open-Label, Multi-Center, Dose Escalation Trial of BI 764532 Given as Monotherapy Administered by Repeated Intravenous Infusions in Patients with Glioma Expressing DLL3	monotherapy; needs DLL3 expression	Inclusion: Tumor histologies: Astrocytoma IDH mutant, CNS WHO Grade 2-4; Oligodendroglioma IDH mutant and 1p19q co-deleted, CNS WHO Grade 2 and 3 Glioblastoma (IDH wild type) 2. Tumors must be positive for DLL3 expression 3. Documented unequivocal progression after radiotherapy and/or chemotherapy with measurable disease by RANO criteria Exclusion: Previous treatment targeting DLL3. Extracranial or leptomeningeal disease. Prior treatment with bevacizumab, other anti-VEGF or anti-angiogenic treatment within 6 months of study treatment.	Open to Accrual
Skin Oncology					
Dr. Valerin	Baoan Huynh	UCI 21-40 A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications	DF6002 as a Monotherapy and in Combination w/ nivo	Inclusion: - Previously tx melanoma, NSCLC, small cell lung, head and neck squamous cell, urothelial, gastric, esophageal, cervical, hepatocellular, Merkel cell, cutaneous squamous cell carcinoma, renal cell, endometrial, triple negative breast cancer (TNBC), ovarian, and prostate cancers - Agrees to pre-treatment biopsy - BRAF (V600) mutation status must be known, if BRAF+, must be treated with BRAF tx before enrolling on trial. Exclusion: - Prior treatment with rhIL2 or with any drug containing an IL2 or IL12 moiety	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Valerin	Natalie Arechiga	UCI 23-197 A Phase I/Ib, First-In-Human, Multi-Part, Open-Label Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of DF6215 in Patients with Advanced (Unresectable, Recurrent, or Metastatic) Solid Tumors	DF6215 (IL-2)	Inclusion: Histologically or cytologically proven locally advanced or metastatic solid tumor, for which no standard therapy exists, or standard therapy has failed Evidence of objective disease (but participation does not require a measurable lesion) Exclusion: Patients must not have received aldesleukin or any other experimental IL-2 based drug Patients with prior anti-PD-1 or anti-PD-L1 treatment are eligible for the study, unless they have experienced any of the following: a) Grade 3 or 4 treatment-related toxicity during an anti-PD-1 or anti-PD-L1 treatment (excluding immune-related endocrinopathies adequately controlled) b) Grade 2 treatment-related toxicity that impacted either the lungs or the nervous system (unless history of neuropathy/paresthesia).	Pending Activation
Lung Oncology					
Dr. Nagasaka	Keagan Buttigieg	UCI 21-241 A Phase I/II Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)	TKI Inhibitor	Inclusion: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation detected by certified assay (i.e. CLIA in the US). Currently on Phase 1 only; received 1 ALK TKI which must be a 2nd or 3rd generation TKI (Ceritinib, alectinib, brigatinib, or lorlatinib).	Open to Accrual
Dr. Ou	Richard Chang	UCI 20-119 An Open-Label Phase I/Ib Study to Evaluate the Safety and Pharmacokinetics of JNJ-73841937 (Lazertinib), a Third Generation EGFR-TKI, as Monotherapy or in Combinations with JNJ-61186372, a Human Bispecific EGFR and cMet Antibody in Participants with Advanced Non-Small Cell Lung Cancer	TKI	Open for Cohort E Exon 19Del or L858R: JNJ-6118637 + Lazertinib (prophylactic anticoagulation for first 4months, relapse on Osimertinib Chemo naïve. Cohort F Exon 19Del or L858R: JNJ-6118632(Amivantamab Monotherapy) relapse on Osimertinib Chemo naïve. Study requires no slots prior to consenting	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Richard Chang	UCI 22-121 A Phase I/II, Open-Label, Multi-Center Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of JIN-A02 in Patients with EGFR Mutant Advanced Non-Small Cell Lung Cancer	TKI	Study requires slots prior to consenting only enrolls EGFR exon 19 del or L858R who have an additional mutation in T790M or C797S	Open to Accrual
Dr. Ou	Keagan Buttigieg	UCI 20-195 Phase I/II Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-C-MET Bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors	Antibody Drug	Inclusion: Patients who have progressed on SOC treatment or are ineligible for, or have refused all other available therapeutic options. Measurable disease per RECIST. Cohort B: NSCLC harboring c-ET exon 14 skipping mutations ≥2L Naïve or pretreated to capmatinib or tepotinib. Cohort G: NSCLC 3L, osimertinib resistant, platinum resistant (participant must have progressed on or after a previous platinum chemotherapy) population. Genetic aberrations in EGFR or c-MET will be retrospectively confirmed by central testing using a validated assay in the expansion phase. For non-first line cohorts there is no limit to the number of prior treatment regimens. Exclusion: Untreated or symptomatic CNS metastases is excluded	Open to Accrual
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	TKI	Allows Prior lines of KRAS G12C TKI, will allow all studies to enroll to this trial. For Part 1 - Dose Escalation, subjects with any KRASG12C solid tumor histology will be enrolled; For backfill cohorts of Part 1 - Dose Escalation, only subjects with a KRASG12C-mutant tumor who have not been previously exposed to a KRASG12C inhibitor (KRASG12Ci-naïve) will be enrolled; For Part 2 - Dose Expansion, subjects with KRASG12C NSCLC and CRC who are KRASG12Ci-naïve will be enrolled. EXCLUSION: *Slots Required prior to consenting	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Jenny Choe	UCI 21-53 A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	TKI	Allows Prior lines of chemo, immunotherapy or biological therapy). Slots Required prior to consenting. EXCLUSION: Individual has received prior treatment with any KRAS G12C small molecule inhibitor. Please refer to Exclusion criteria to confirm which cohorts applies. Cohorts B9 and Part G only, Individual received prior systemic therapy (chemotherapy, immunotherapy, or biological therapy) for advanced or metastatic disease, except as allowed in Inclusion Criterion #4.	Open to Accrual
Dr. Ou	Celest Ramirez	UCI 18-78 A Phase I/II Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation	TKI	Phase 2 Cohort D: Other solid tumors outside of NSCLC/CRC; unresectable or metastatic disease. Phase 1b 1st-line treatment for NSCLC; patients with limited brain metastases; CRC patients for combination with cetuximab. No available treatment or patient declines therapy Allows prior systemic therapy(Chemo, immune or investigational therapy) EXCLUSION: Phase 2, patients must have received at least platinum chemotherapy and checkpoint inhibitor therapy AND no prior treatment with targeted KRAS G12C therapy. *Slots Required prior to consenting(Currently no slots available)	Open to Accrual
Dr. Ou	Oliver Quines	UCI 22-87 Phase I/IB Multicenter Open-Label Study of RMC-6236 in Subjects with Advanced Solid Tumors Harboring Specific Mutations in KRAS	TKI	Participating in PART 2 dose expansion only and not participating in food effect portion of the study NSCLC: progressed on or intolerant to anti-PD(L)1 and platinum-based chemotherapy; no more than 3 lines of prior systemic therapy for metastatic disease PDAC: progressed on or intolerant to either fluoropyrimidine-based or gemcitabine-based therapy CRC: progressed on or intolerant to fluoropyrimidine, oxaliplatin, and irinotecan and with anti- PD(L)1 therapy for patients with microsatellite unstable/mismatch repair-deficient tumors Melanoma: progressed on or intolerant to anti-PD(L)1 and anti-CTLA4 Gynecological cancers (eg, ovarian, cervical, uterine [including endometrial], vaginal, vulvar): progressed on or intolerant to platinum-based chemotherapy Other solid tumors: (1) progressed on or intolerant to standard therapy, or (2) in the opinion of the investigator, not a candidate for or unlikely to derive significant clinical benefit from standard therapy, or (3) declines standard therapy, or (4) no standard therapy exists	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Keagan Buttigieg	UCI 21-47 A Phase I/II Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)	TKI	INCLUSION: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with documented ROS1 rearrangement. PT with ROS1 fusion received at least 1 prior ROS1 TKI other ROS1-positive solid tumors must have progressed on any prior therapy (includes, but is not limited to, patients who have progressed on prior ROS1 TKIs). Any number of prior platinum-based chemotherapies with or without immunotherapy is allowed. Cohort 2a: naive to TKI therapy and up to one prior platinum based chemo w/wo immuno. Cohort 2b: received 1 prior ROS1 TKI therapy (crizotinib or entrectinib) no prior platinum based chemo or mmunotherapy. Cohort 2C: 1 prior ROS1 TKI therapy and 1 prior platinum based chemo or immuno. Cohort 2D: 2prior ROS1 TKI and up to 1 prior platinum based chemo w/wo immuno. Cohort 2E: progressed on any prior therapies.	Open to Accrual
Soild Tumors/Basket Trials					
Dr. Parajuli	Juan Miranda	UCI 22-09 A Phase Ib, First-In-Human, Dose Escalation and Expansion, Multicenter Study of XMT-1660 in Participants with Solid Tumors	Antibody drug conjugate	Inclusion: Proven recurrent or advanced solid tumor and has disease progression after treatment with available anti-cancer therapies TNBC inclusion: DES and Backfill Cohorts: Participant has received at least 2 lines of systemic therapy in a locally advanced or metastatic BC setting. EXP: Participant has received 1 to 3 prior lines of chemotherapy in a locally advanced or metastatic BC setting. HR+, HER2- inclusion: DES and Backfill Cohorts: Participant has received at least 1 line of systemic therapy, which must have included a CDK4/6 inhibitor(s) and ET in an advanced or metastatic BC setting. EXP: Participant must have received prior therapy with a CDK4/6 inhibitor(s) combined with ET in any setting Exclusion: Participant has received prior treatment with another ADC containing an auristatin or maytansinoid payload Participant has had major surgery within 28 days of starting study treatment; systemic anti-cancer therapy within the time period of 28 days or 5 half-lives of the prior therapy before starting study treatment (14 days or 5 half-lives for small molecule targeted therapy), whichever is less; or palliative radiation therapy within 14 days of starting study treatment.	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Parajuli	Juan Miranda	UCI 22-156 A Phase Ib Study of TBio-4101 (Autologous Selected and Expanded Tumor-Infiltrating Lymphocytes [TIL]) and Pembrolizumab in Patients with Advanced Solid Tumor Malignancies (STARLING)	Tumor infiltrating lymphocyte therapy	Inclusion: Patients with breast cancer must have relapsed on at least one and no more than three prior treatments for metastatic disease (adjuvant/neoadjuvant therapy will not count toward the three prior therapies limit.) Patients with HER2-positive disease must have received a HER2-containing regimen. Patients with BRCA mutations must have previously been treated with a targeted therapy. Exclusion: Patients with known active central nervous system (CNS) metastases (Patients with previously treated brain metastases may participate provided they are radiologically stable) Patients with a known additional malignancy that is progressing or has required active treatment within the past 3 years.	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 • 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	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Dayyani	Peter Yang	UCI 22-221 A First-in-human Phase I, Non-randomized, Open-label, Multi-center Dose Escalation Trial of Bi 765049 and Bi 765049 + Ezabenlimab Administered by Repeated Intravenous Infusions in Patients with Malignant Solid Tumors Expressing B7 H6	(Central B7-H6 testing) HCC and Pancreatic (also NSCLC, HNSCC, CRC, and gastric)	CRC patients do not require prescreening consent	Open to Accrual
Dr. Dayyani	My Ha Nguyen	ETCTN 10495 Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations	DS-8201a + Neratinib	Inclusion: • Patients must have HER2-positive as determined by any one or more of the following: ▯ HER2-overexpressing defined by IHC 3+ ▯ ERBB2 amplification by ISH or next generation sequencing as determined by any CLIA certified lab ▯ A known HER2 activation mutation • Patients must have received at least 1 prior line of therapy in the advanced/metastatic setting. No limitation on number of prior therapies Exclusion: • Prior treatment with neratinib or DS-8201a	Open to Accrual
Dr. Lee	Peter Yang	ETCTN 10579 Phase I Trial of ZEN003694 (ZEN-3694) in Combination with Capecitabine in Patients with Solid Tumors	ZEN003694 (ZEN-3694) + capecitabine	<u>Dose Escalation additional criteria:</u> ▯atients must have histologically confirmed cancer that is metastatic or unresectable and must have progressed on standard therapies whichwould ▯ave included 5-FU or capecitabine <u>Dose Expansion additional criteria:</u> ▯atients must have histologically confirmed CRC that is metastatic or unresectable and must have progressed on standard therapies which would have ▯ncluded 5-FU or capecitabine *pre and post treatment biopsies are required for specific cohorts	Open to Accrual
Dr. Dayyani	My Ha Nguyen	UCI 23-109 A Phase Ib/II Open-Label Study of Disitamab Vedotin Monotherapy or in Combination with Other Anticancer Therapies in Solid Tumors	Disitamab Vedotin + Tucatinib	Escalation phase: Previously treated advanced GC/GEJC or Breast Cancer (HER2-expressing) Expansion phase: Expansion Phase Cohort B HER2+ 3L or higher Breast Cancer, HER2-low 2L GC/GEJC	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Tewari	Jiana Ejbara	UCI 22-42 Phase I/II, Open-label Dose Escalation and Dose Expansion Study of TransCon TLR7/8 Agonist, Alone or in Combination with Pembrolizumab in Participants with Locally Advanced or Metastatic Solid Tumor Malignancies	TransCon Toll like receptor (TLR) 7/8 agonist	• Participants must have histologically confirmed locally advanced, recurrent or metastatic solid tumor malignancies that cannot be treated with curative intent (surgery or radiotherapy). - Patients in neoadjuvant cohorts are exempt. • At least 2 lesions of measurable disease per RECIST 1.1, unless specified otherwise in the selection criteria – at least 1 lesion that is safely accessible for intratumoral injection and 1 lesion that is not injected (at least initially). • Lesion(s) to be injected must be measurable and greater than or equal to 15 mm in the longest diameter at initial selection. Exclusion: Participants who have been previously treated with a TLR agonist (excluding topical agents for unrelated disease) are not eligible. Other active malignancies within the last 2 years are excluded. Known hypersensitivity to any component of TransCon TLR7/8 Agonist or pembrolizumab.	Open to Accrual
Dr. Tewari	Jiana Ejbara	UCI 22-77 Phase I First-in-Human Study to Explore the Safety, Tolerability and Pharmacokinetics of AMG 794 in Subjects with Claudin 6-Positive Advanced/Metastatic Non-Squamous Non-Small Cell Lung Cancer or Epithelial Ovarian Cancer and Other Malignant Solid Tumor Indications	AMG794 half-life extended (HLE) BiTE molecule targeting CLDN6	Inclusion: • Subjects with histologically or cytologically documented malignant solid tumor diseases expressing CLDN6 including but not limited to NSCLC, EOC, testicular germ cell cancer, uterine endometrial cancer, or triple negative breast cancer, that is metastatic or unresectable at screening time point. Subjects should have exhausted available SOC systemic therapy or should not be candidates for such available therapy. • For dose expansion cohorts: Subjects with at least 1 measurable lesion ≥ 10 mm which has not undergone biopsy within 3 months of screening scan. This lesion cannot be biopsied at any time during the study. Exclusion: • History of other malignancy within the past 2 years, with the following exceptions: - Malignancy treated with curative intent and with no known active disease present for ≥ 2 years before enrollment and understood to be at low risk for recurrence by the treating physician. - Adequately treated cervical carcinoma in situ without evidence of disease. - Adequately treated breast ductal carcinoma in situ without evidence of disease.	Suspended

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Tewari	Jiana Ejbara	UCI 22-78 A Phase I Study of KSQ-4279 Alone and in Combination in Patients with Advanced Solid Tumors	KSQ-4279 +/- Olaparib or Carboplatin Targeting deleterious mutation (germline or somatic)	Inclusion: Deleterious mutation (germline or somatic) in at least 1 of the following genes involved in the HRR pathway Histologically diagnosed recurrent or persistent high grade serous ovarian cancer (including primary peritoneal and/or fallopian tube cancer) Received prior platinum-based chemotherapy Patients may have platinum-sensitive or resistant disease Exclusion: Ongoing Grade 2 or greater toxicity, except alopecia, related to any prior treatment (ie, chemotherapy, targeted therapy, radiation, or surgery). Chemotherapy or small molecule-targeted therapy < 2 weeks prior to first dose of study treatment. Known hypersensitivity to study therapies and its excipients.	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	MRG004A (TF ADC)	• 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 central IHC	Open to Accrual
Dr. Dayyani	Jasmine Balangue	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	CB-03-10 (Androgen and glucocorticoid antagonist)	• Part 1 (Dose Escalation): histologically or cytologically confirmed relapsed or refractory advanced or metastatic solid tumor of any origin, not amenable to standard of care therapy • Measurable or evaluable disease per RECIST v1.1 criteria	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Valerin	Baoan Huynh	UCI 21-40 A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications	DF6002 as a Monotherapy and in Combination w/ nivo	Inclusion: - Previously tx melanoma, NSCLC, small cell lung, head and neck squamous cell, urothelial, gastric, esophageal, cervical, hepatocellular, Merkel cell, cutaneous squamous cell carcinoma, renal cell, endometrial, triple negative breast cancer (TNBC), ovarian, and prostate cancers - Agrees to pre-treatment biopsy - BRAF (V600) mutation status must be known, if BRAF+, must be treated with BRAF tx before enrolling on trial. Exclusion: - Prior treatment with rhIL2 or with any drug containing an IL2 or IL12 moiety	Open to Accrual
Dr. Dayyani	My Ha Nguyen	ETCTN 10358 Phase I/IB Study of DS-8201a in Combination with ATR Inhibition (AZD6738) in Advanced Solid Tumors with HER2 Expression (DASH Trial)	DS8201a + AZD6738	• Patients must have HER2-positive or HER2-expressing tumors determined by a CLIA-certified laboratory ▣ HER2 expression (1-3+) by IHC locally and confirmed centrally OR ▣ HER2 expression (1-3+) by IHC tested centrally OR ▣ HER2 amplification based on FISH or Next Generation Sequencing • Must have received at least one line of systemic chemotherapy for either locally advanced or metastatic disease and should have either progressed on this therapy or been intolerant to this therapy • For tumors where anti-HER2 therapy is standard of care, patients must have progressed on at least 1 line of anti-HER2 therapy if eligible. For patients where DS8201a is approved as standard of care, prior treatment with DS8201a is not allowed • Dose-escalation phase: Must have histologically confirmed advanced solid tumor including but not restricted to breast cancer, gastric or gastroesophageal cancer, colon cancer, endometrial cancer, salivary gland tumors, and hepatobiliary tumors • Dose-expansion phase: Must have histologically confirmed advanced/metastatic gastroesophageal cancer (cohort A) or colorectal cancer (cohort B)	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Keagan Buttigieg	UCI 21-241 A Phase I/II Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)	TKI Inhibitor	Inclusion: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation detected by certified assay (i.e. CLIA in the US). Currently on Phase 1 only; received 1 ALK TKI which must be a 2nd or 3rd generation TKI (Ceritinib, alectinib, brigatinib, or lorlatinib).	Open to Accrual
Dr. Ou	Keagan Buttigieg	UCI 20-195 Phase I/II Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-C-MET Bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors	Antibody Drug	Inclusion: Patients who have progressed on SOC treatment or are ineligible for, or have refused all other available therapeutic options. Measurable disease per RECIST. Cohort B: NSCLC harboring c-ET exon 14 skipping mutations ≥2L Naïve or pretreated to capmatinib or tepotinib. Cohort G: NSCLC 3L, osimertinib resistant, platinum resistant (participant must have progressed on or after a previous platinum chemotherapy) population. Genetic aberrations in EGFR or c-MET will be retrospectively confirmed by central testing using a validated assay in the expansion phase. For non-first line cohorts there is no limit to the number of prior treatment regimens. Exclusion: Untreated or symptomatic CNS metastases is excluded	Open to Accrual
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	TKI	Allows Prior lines of KRAS G12C TKI, will allow all studies to enroll to this trial. For Part 1 - Dose Escalation, subjects with any KRASG12C solid tumor histology will be enrolled; For backfill cohorts of Part 1 - Dose Escalation, only subjects with a KRASG12C-mutant tumor who have not been previously exposed to a KRASG12C inhibitor (KRASG12Ci-naïve) will be enrolled; For Part 2 - Dose Expansion, subjects with KRASG12C NSCLC and CRC who are KRASG12Ci-naïve will be enrolled. EXCLUSION: *Slots Required prior to consenting	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Jenny Choe	UCI 21-53 A Phase Ia/Ib Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors	TKI	Allows Prior lines of chemo, immunotherapy or biological therapy). Slots Required prior to consenting. EXCLUSION: Individual has received prior treatment with any KRAS G12C small molecule inhibitor. Please refer to Exclusion criteria to confirm which cohorts applies. Cohorts B9 and Part G only, Individual received prior systemic therapy (chemotherapy, immunotherapy, or biological therapy) for advanced or metastatic disease, except as allowed in Inclusion Criterion #4.	Open to Accrual
Dr. Ou	Celest Ramirez	UCI 18-78 A Phase I/II Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation	TKI	Phase 2 Cohort D: Other solid tumors outside of NSCLC/CRC; unresectable or metastatic disease. Phase 1b 1st-line treatment for NSCLC; patients with limited brain metastases; CRC patients for combination with cetuximab. No available treatment or patient declines therapy Allows prior systemic therapy(Chemo, immune or investigational therapy) EXCLUSION: Phase 2, patients must have received at least platinum chemotherapy and checkpoint inhibitor therapy AND no prior treatment with targeted KRAS G12C therapy. *Slots Required prior to consenting(Currently no slots available)	Open to Accrual
Dr. Ou	Oliver Quines	UCI 22-87 Phase I/IB Multicenter Open-Label Study of RMC-6236 in Subjects with Advanced Solid Tumors Harboring Specific Mutations in KRAS	TKI	Participating in PART 2 dose expansion only and not participating in food effect portion of the study NSCLC: progressed on or intolerant to anti-PD(L)1 and platinum-based chemotherapy; no more than 3 lines of prior systemic therapy for metastatic disease PDAC: progressed on or intolerant to either fluoropyrimidine-based or gemcitabine-based therapy CRC: progressed on or intolerant to fluoropyrimidine, oxaliplatin, and irinotecan and with anti- PD(L)1 therapy for patients with microsatellite unstable/mismatch repair-deficient tumors Melanoma: progressed on or intolerant to anti-PD(L)1 and anti-CTLA4 Gynecological cancers (eg, ovarian, cervical, uterine [including endometrial], vaginal, vulvar): progressed on or intolerant to platinum-based chemotherapy Other solid tumors: (1) progressed on or intolerant to standard therapy, or (2) in the opinion of the investigator, not a candidate for or unlikely to derive significant clinical benefit from standard therapy, or (3) declines standard therapy, or (4) no standard therapy exists	Open to Accrual

MD	CRC	Study Title	Mech of Action	Broad Eligibility	Study Status
Dr. Nagasaka	Keagan Buttigieg	UCI 21-47 A Phase I/II Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)	TKI	INCLUSION: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with documented ROS1 rearrangement. PT with ROS1 fusion received at least 1 prior ROS1 TKI other ROS1-positive solid tumors must have progressed on any prior therapy (includes, but is not limited to, patients who have progressed on prior ROS1 TKIs). Any number of prior platinum-based chemotherapies with or without immunotherapy is allowed. Cohort 2a: naive to TKI therapy and up to one prior platinum based chemo w/wo immuno. Cohort 2b: received 1 prior ROS1 TKI therapy (crizotinib or entrectinib) no prior platinum based chemo or mmunotherapy. Cohort 2C: 1 prior ROS1 TKI therapy and 1 prior platinum based chemo or immuno. Cohort 2D: 2prior ROS1 TKI and up to 1 prior platinum based chemo w/wo immuno. Cohort 2E: progressed on any prior therapies.	Open to Accrual
Dr. Dayyani	Krissy Ghio/ Jensen Koff	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.	Open to Accrual