Neoadjuvant - Nasopharyngeal					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Dr. Nabar	Krissy Ghio	NRG-HN001 Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)	Adjuvant Cisplatin/5FU vs Gemcitabine/Paclitaxel	Must have detectable EBV DNA Biopsy proven stage II-IVB nasopharyngeal cancer with no distant metastasis Must not have prior invasive malignancy	Open to accrual

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Celest Carrillo x509-2738

Adjuvant - Squamous Cell Carcinoma of Head and Neck					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Dr. Nelson	Krissy Ghio	UCI 21-107: A Phase II, Open-Label, Multi-Center Study of PDS0101 (R-DOTAP [Versamune] + HPVmix) and Pembrolizumab (KEYTRUDA) Combination Immunotherapy in Subjects with Recurrent and/or Metastatic Head and Neck Cancer and High-Risk Human Papillomavirus-16 (HPV16) Infection	PDS0101 injection + Pembrolizumab	**Inclusion:** Checkpoint-naïve subjects: Have a history of histologicallyconfirmed diagnosis of squamous cell cancer of the head and neck (HNSCC) that is recurrent, metastatic, or persistent with: a. Confirmed HPV16 infection b. Confirmed tumor PDL1 expression defined as a combined positive score (CPS) ≥1 using the FDAapproved Dako PD-L1 immunohistochemistry (IHC) 22C3 PharmDx Assay. c. No prior receipt of any immunological therapy for metastatic disease Checkpoint experienced subjects have a history of histologically-confirmed diagnosis of HNSCC that is recurrent, metastatic, or persistent with: a. Confirmed HPV16 infection b. Characterization of tumor PDL1 expression using the FDA-approved PD-L1 IHC 22C3 PharmDx Assay. c. Receipt of prior treatment with checkpoint inhibitors as a single agent or in combination, and have received at least 2 doses of the agent or a minimum of 6 weeks on treatment d. Have documented clinical progression or recurrence that has been radiologically confirmed **Exclusion:** Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis. Subjects with previously treated brain metastases may participate provided they are radiologically stable, ie, without evidence of progression for at least 4 weeks by repeat imaging	Pending activation

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Dr. Nabar	Krissy Ghio	RTOG-1216: Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk Squamous Cell Cancer of the Head and Neck	Group 1: Radiation + cisplatin Group 3: Radiation + doctaxel + cetuximab Group 4: Radiation + cisplatin + atezolizumab	Exclusion Criteria: -Prior systemic therapy (chemotherapy is allowed if for a different cancer) -Prior immunotherapy -Prior radiotherapy to the region	Open to accrual

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Basket Trials					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Dr. Bota	Mehir Tharani	ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)	Mutation based treatment	Positive for Specific Mutations	Open to accrual
Dr. Ou	Anabel Serwanska	UCI 18-21: A Phase I/II Study of Oral LOXO-292 in Patients with Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation (LIBRETTO-001)	RET Receptor Tyrosine Kinase inhibitor that harbors RET alterations	Patient with RET fusion-positive solid tumor or an advanced solid tumor that harbors a RET gene alteration (excluding synonymous, frameshift, or nonsense mutation)	Open to accrual
Dr. Ou	Celest Carrillo	UCI 18-78: A Phase I/II Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation	KRAS G12C	Solid tumor malignancy; unresectable or metastatic disease; measurable lesions per RECIST 1.1; no available treatment or patient declines therapy EXCEPT phase 2, patients must have received at least platinum chemotherapy and checkpoint inhibitor therapy;	Open to accrual

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Basket Trials					
Dr. Ou	Oliver Quines	UCI 18-14: A Phase I, Open-Label, Multicenter Dose Escalation Study of RMC-4630 Monotherapy in Adult Patients with Relapsed/Refractory Solid Tumors	Dose Expansion: RTK mutations, amplifications or rearrangements, KRASG12, BRAF Class 3, or NF1 LOF mutations	Have advanced solid tumors that have failed, are intolerant to, or are considered ineligible for standard of care anticancer treatments including approved drugs for oncogenic drivers in their tumor type	Open to accrual
Dr. Bota	Mehir Tharani	UCI 19-99 A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Enzastaurin Added to Temozolomide During and Following Radiation Therapy in Newly Diagnosed Glioblastoma Patients Who Possess the Novel Genomic Biomarker DGM1	Double blinded treatment with RT and Temozolomide plus Enzastaurin/Matching Placebo	Newly diagnosed supratentorial glioblasoma (IDH mutant is excluded) Randomization must occur within 5 weeks of resection (patients undergoing biopsy only are excluded) No prior RT to the brain	Open to accrual

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Basket Trials					
Dr. Brém	Blake Johnson	ECOG-EA4151 A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative Firs	Auto HCT + Rituximab vs Rituximab	Tumor tissue from original diagnostic biopsy required for pre-registration tissue submission; 18-70 years old; Must have cyclin D1 by immunohistochemical stains and/or t(11;14) by cytogenetics or FISH.	Open to accrual

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Basket Trials					
Dr. Bota	Mehir Tharani	UCI 18-83/Bota Pilot Study of Mirtazapine for the Dual Treatment of Depression and Temozolomide-Induced Nausea and Vomiting (CINV) in Newly-Diagnosed High-Grade Glioma Patients on Temozolomide Therapy	Mirtazapine	No prior treatment with temozolomide TMZ, Histologically confirmed diagnosis of glioma, Karnofsy Performance Score (KPS) of at least 60	Open to accrual
Dr. Ou	Oliver Quines	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	MCLA-129	Histologicaly or cytologically confirmed solid tumors with evidence of metastatic or locally advance unresected disease that is incurable. Exclusion: CNS metastases that are untreated or symptomatic or require radiation, surgery or continued steroid therapy	Open to accrual
Dr. Tewari	Kenya Gomez	UCI 20-88/A Phase Ib Study of ASP1951, a GITR Agonistic Antibody, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors	ASP1951 Pembrolizumab	• Subject has locally-advanced unresectable) or metastatic sold tumor malignancy (no limit to the number of prior treatment regimens) that is confirmed by available pathology records or current biopsy	Open to accrual
Dr. Ou	Anabel 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

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Basket Trials					
Dr. Ou	Oliver Quines	UCI 20-185: A Phase I/IB, Open-Label, Dose Escalation and Expansion Study of SBT6050 Alone and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Expressing HER2	SBT6050 (anti-HER2) +/− pembrolizumab	Part 1 (Dose Escalation Phase): • HER2-expressing (IHC 2+ or 3+) or HER2-amplified advanced cancers Part 2 (Dose Expansion Phase) for Locally Advanced and/or Metastatic Cancers • Cohort A: HER2-positive (IHC 3+ or IHC2+/HER2 amplified) breast cancer • Cohort B: HER2-low-expressing (IHC 2+/HER2 non-amplified) breast cancer • Cohort C: HER2-positive (IHC 3+ or IH2+/HER2 non-amplified) gastric or GEJ cancer • Cohort D: HER2-expressing (IHC 3+ or 2+) or HER2-amplified NSCLC • Cohort E: Other HER22-expressing (IHC 3+ or 2+) or HER2-amplified malignant solid tumors Part 3 and 4 (Dose Expansion Phase) for Locally Advanced and/or Metastatic Cancers • HER2-positive (IHC 3+ or IHC 2+/HER2 amplified) breast cancer, gastroesophageal cancer • HER2-expressing (IHC 3+ or 2+) or HER2 amplified colorectal cancer, endometrial cancer, biliary tract cancer, cholangiocarcinoma, NSCLC, HNSCC, urothelial cancer	Open to Accrual

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Basket Trials					
Dr. Ou	Celest Carrillo	UCI 20-194: A Phase I/II, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of D-1553 in Subject with Advanced or Metastatic Solid Tumors with KRasG12C Mutation	D-1553 (KRAS inhibitor)	• Histologically-proven, locally advanced, unresectable and/or metastatic solid tumor • KRasG12C mutation in tumor tissue or blood, pleural effusion, or other samples containing cancer cells or DNA (Phase I - historical local lab results < 5 years may be used; Phase II - must be tested centrally)	Open to accrual
Dr. Ou	Oliver Quines	UCI 21-12: A Phase I/IB, Open-Label, Multicenter, Dose-Escalation Study of RMC-5552 Monotherapy in Adult Subjects with Relapsed/Refractory Solid Tumors	RMC-5552 (mTORC1 inhibitor)	Dose-Escalation Phase: participants with relapsed or refractory solid tumors who have failed, or are intolerant to, or are considered ineligible for standard-of-care therapies Dose-Expansion Phase: participants with relapsed or refractory solid tumors harboring certain specific mutations/rearrangements that result in hyperactivation of the mTOR pathway (e.g. PIK3CA, PTEN, TSC1/2, STK11, MTOR, MYC, MAPK - please contact CRC for specific aberrations)	Open to accrual

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Basket Trials					
Dr. Valerin	Parvin Keshtmand *714-509-2739*	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	**Dose Escalation Phase:** • 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, Merkle cell, cutaneous squamous cell carcinoma, RCC, endometrial, TNBC, ovarian, and prostate	Open to Accrual