

	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)	-	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		
	Adjuvant - Squamous Cell Carcinoma of Head and Neck						
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status		
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		Exclusion Criteria: -Prior systemic therapy (chemotherapy is allowed if for a different cancer) -Prior immunotherapy -Prior radiotherapy to the region	Open to accrual		



	Basket Trials						
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status		
Dr. Bota	I 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. Zhu	Anabel Serwanska	UCI 16-96: A Phase I Study of the Highly- selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors	RET rearrangement/ fusion or mutation	Non-resectable advanced solid tumor that has progressed following SOC therapy Has a known primary driver alteration other than RET	Open to accrual		
Dr. Ou	Leo Inocencio	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 accural		



	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	amplifications or rearrangements, KRASG12, BRAF	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. O'Brien	Mashal Chhotani	NCICOVID: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study	Data, specimen, and image collection	<ul> <li>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</li> <li>Must be currently testing for SARS-CoV-2 or has         had first positive test &lt; 14 days</li> </ul>	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/Mat ching 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		



	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		
Dr. Bota	Sherin Matthew	UCI 20-65 EF-32: Randomized, Open-Label Study of Tumor Treating Fields (Optune®, 200kHz) Concomitant with Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma	Treatment with TTFields concomitantly with RT and TMZ followed by TTFields and maintenance TMZ or Treatment with RT and TMZ followed by TTFields and maintenance TMZ	Not available yet	Pending Activation		



	Basket Trials					
Dr. Bota	Joanne Bacling x509-2759	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	Histologically 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	Anabei Serwanska 714-456-8279	UCI 20-68: A Phase II Study of Seribantumab (FTN100) in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors	Seribantumab (ERBB inhibitor)	<ul> <li>NRG1 gene fusion</li> <li>Advanced or metastatic (Stage IIIB or IV) or unresectable</li> <li>2nd or 3rd line treatment (no previous ERBB/HER2/HER3 treatment for cohort 1)</li> </ul>	Open to accrual	



	Basket Trials						
Dr. Ou	Oliver Quines 714-456-6244	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	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	



	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		