UCI Chao Family Comprehensive Cancer Center — Newport Clinical Trials

PI	Newport Sub-I	Newport CRC	CRC @ Orange	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Breast-Adjuvant							
Parajuli	Nabar Coluzzi Mehta Nanci	Nidhisha Patel (714)509-2430	Nidhisha Patel (714)509-2430	A011801: The COMPASSHER2 Trials (Comprehensive Use of Pathologic Response Assessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib	anti-PD-1 inhibitor (immunotherapy)	Patients must have HER2+ breast cancer with residual disease after NACT No prior treatment with TDM-1	Open to accrual
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Breast - Metastatic HER2-							
Parajuli	Mehta Coluzzi Nabar Nanci	Nidhisha Patel (714)509-2430	Nidhisha Patel (714)509-2430	ETCTN 10287: A Randomized Phase I/II Trial of Fulvestrant and Abemaciclib in Combination with Copanlisib (FAC) versus Fulvestrant and Abemaciclib Alone (FA) for Endocrine-Resistant, Hormone Receptor Positive, HER2 Negative Metastatic Breast Cancer	Pan-class I PI3K inhibitor	•HER2-, metastatic breast cancer •No more than one chemotherapy line in metastatic setting •For patients enrolling on Phase E portion of the study: -Must have resistance to endocrine therapy in metastatic setting -No prior treatment w/ CDK 4/6 inhibitor, Fulvestrant, or PI3K inhibitor in metastatic setting -No brain metastasis	Open to Accrual
Parajuli	Coluzzi Mahdavi Mehta Nanci Nabar	Julia Ahumada (714) 456-6907	Julia Ahumada (714) 456-6907	SWOG S2007: A Phase II Trial of Sacituzumab Govitecan for Patients with HER2-Negative Breast Cancer and Brain Metastases	Antibody drug conjugate	HER2- invasive breast cancer with brain metastasis CNS progression after previous CNS-directed therapy	Open to accrual
Breast-Metastatic Triple Negative							
Parajuli	Coluzzi Nanci Mehta Nabar	Nidhisha Patel (714)509-2430	Nidhisha Patel (714)509-2430	ETCTN 10146: Randomized Phase II Clinical Trial of Nab-Paclitaxel + MEDI4736 (Durvalumab) + Tremelimumab + Neoantigen Vaccine vs. Nab-Paclitaxel + MEDI4736 (Durvalumab) + Tremelimumab in Patients with Metastatic Triple Negative Breast Cancer	IgG monoclonal antibody + IgG2 monoclonal antibody + synthetic neoantigen targeting vaccine	Metastatic triple negative breast cancer Must be PD-L1 negative and have not received any prior therapies for metastatic TNBC Must be considered a candidate for first line carboplatin + gemcitabine	Open to Accrual
GU							
Kalebasty	Uchio Hugen	Amanda Macaraeg (714) 456-6264	Amanda Macaraeg (714) 456-6264	S1823: A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients With Newly Diagnosed Germ Cell Tumor	N/A	Newly diagnosed germ cell tumor within 42 days of study registration	Open to accrual

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Dayyani	Lee Zell	Kristian Ghio (714) 456-6528	Kristian Ghio (714) 456-6528	UCI 21-110: Phase Ib/II Study of Agents Targeting the Mitogen-Activated Protein Kinase Pathway in Patients with Advanced Gastrointestinal Malignancies (HERKULES-3)	anti-ERK1/2 + Cetuximab + Encorafenib	• Histologically or cytologically confirmed metastatic CRC • Dose Escalation cohorts: must have disease progression after at least 1 systemic regimen. Prior regimens must contain the following (prior regorafenib or TAS-102 prohibited): - All patients: 5-FU or capecitabine, oxaliplatin and/or irinotecan, bevacizumab - Patients with MSI-H or dMMR CRC: pembrolizumab or nivolumab • Please contact clinical research coordinator for latest cohort status and updates	**Open to accrual**
Zell	Nabar Cho Jafari Neumann Dayyani Lee Carmichael	Luisa Meijia Aguilar (714) 509-2739	Luisa Mejia Aguilar (714) 509-2739	NRG-GI005: Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)	ctDNA as prognostic biomarker	• Histologically/pathologically confirmed stage IIA adenocarcinoma of the colon with at least 12 lymph nodes examined at the time of surgical resection • Appropriate for active surveillance (i.e., no adjuvant chemotherapy) at the discretion of the evaluating oncologist based on current practice patterns	Open to accrual
Zell	Nabar Cho Jafari Lee Dayyani Carmichael Mills Valerin	Amber Luna (714) 456-8571	Amber Luna (714) 456-8571	S0820: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III	Eflornithine: Ornithine decarboxylase (ODC) inhibitor; Sulindac: COX I/II inhibitor	• Stage 0-III colon or rectal adenocarcinoma treated per SOC with resection alone or in combination with radiation or chemotherapy • Registration within 180-456 (inclusive) days of primary resection • NED (post-operative colonoscopy)	Open to accrual
Dayyani	Lee Neumann Valerin Zell Cho Elguza	Luisa Mejia Aguilar (714) 509-2739	Luisa Mejia Aguilar (714) 509-2739	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 FU-containing regimen	Open to accrual

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GI							
Dayyani	Lee Zell	Nicole Ferrand (714) 509-2938	Nicole Ferrand (714) 509-2938	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 •Child-Pugj A-B7(B7 based on albumin allowed) •Not a candidate for resection or transplantion •Must have at least	Open to accrual
Dayyani	Lee	Miranda Duron (714) 509-6598	Miranda Duron (714) 509-6598	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/bev vs atezo/bev + tiragolumab vs atezo/bev + tocilizumab	•1st line systemic treatment •Histology/Cytology confirmed locally advance 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
Neuro							
Bota	Castillo Chow Hsu Myung Turner	Sherin Mathew (714) 509-2370	Sherin Mathew (714) 509-2370	UCI 16-56: Phase II, Single Arm Study Of NOVOTTF-200A In Bevacizumab-Naive Subjects With Recurrent WHO Grade III Malignant Astrocytoma	TTF device	1p/19q Co-deletion and IDH Mutation. Newly diagnosed and ≤ 3 months from surgical diagnosis. Histological evidence of WHO grade III anaplastic glioma or WHO grade II low grade glioma w	Open to accrual
Heme Trials							
Brem	Pinter-brown Mahdavi Nabar	Stephanie Osorio (714) 509-2970	Stephanie Osorio (714) 509-2970	SWOG-S1925: Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therpay with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study	BCL2 inhibitor + anti-CD20 monoclonal antibody	Newly diagnosed CLL or SLL within 12 months of registration. Age ≥ 18 years. Participants must have CLL-International Prognostic Index (CLL-IPI) Score ≥ 4 and/or complex cytogenetics (defined as 3+ chromosomal abnormalities). Prior therapy with anti CD20 monoclonal antibodies is not allowed.	Open to accrual

Correlative Trials							
Dayanni	Cho Lee ,J Neumann Samarasena Smith Valerin Zell	My Ha Nguyen (714) 509-2704	My Ha Nguyen (714) 509-2704	UCI 19-55: A Non-Interventional Biomarker Study on the Molecular Evaluation of Archival Tumor Tissue in Subjects with Gastric Cancer	MUC17 and CLDN18.2 tissue testing	• Archival tumor tissue sample for central lab for MUC17 and CLDN18.2 testing • Locally advanced or metastatic gastric adenocarcinoma at time of enrollment: T2-T4b/N0-3b/M0-M1 • See: UCI 19-56 for companion interventional study	Open to accrual

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Correlative/Non-Treatment Trial							
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Parajuli	Kessenbrock Lane	TBD	Billy Joel Sanchez (714) 456-7242	UCI 17-05: Understanding Intratumoral Heterogeneity Using Single Cell RNA Sequencing	Tumor heterogeneity and cell atlas delineating BRCA1-driven breast tumor initiation and progression in single cell resolution	Breast Cancer patients irrespective of the Hormonal or Her-2 receptor expression status and across Stages I, II, III and IV who are BRCA 1 positive and will undergo breast or axillary node biopsy, definite surgery or prophylactic surgery (study group).	Suspended
Senthil	Dayyani Lee Zell	Corrinne Maton (714) 509-2779	Corrinne Maton (714) 509-2779	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	Blood Collection	Must have immunotherapy-naïve histologically, radiologically, or cytologically confirmed cancer (e.g. melanoma, HCC, colorectal, appendix or gastric cancer)	Open to accrual
Parajuli	Coluzzi Lane Nanci	Julia Ahumada (714) 456-6907	Julia Ahumada (714) 456-6907	UCI 18-136: Blood Collection Protocol for the Analysis of Exosomes in Patients with Breast Cancer	Blood collection	Patient with Stage I, Stage II, Stage III and Stage IV Breast cancer (HR+, HER2+, triple positive or triple negative)	Open to Accrual
Supportive Care/Diagnostic							
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Bota	Myung Lomax	Mehir Tharani (714) 509-2643	Tharani Mehir (714) 509-2643	UCI 18-83: 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	Antidepressant	Histologically confirmed diagnosis of glioma -No prior treatment with temozolomide TMZ -Patient will receive temozolomide TMZ therapy as part of their standard treatment.	Open to accrual