UCI Chao Family Comprehensive Cancer Center

UCI Health Cancer Center — Newport Clinical Trials

Breast-Adjuvant							
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	Nabar Coluzzi Mehta Nanci	Elizabeth Afu	Dezurline Garcia	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

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PI	Newport Sub-I	Newport CRC	CRC @ Orange	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Breast - Metastatic HER2+							
Parajuli	Coluzzi Mahdavi Mehta Nanci	Elizabeth Afu	Dezurline Garcia	NRG-BR004: A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer	PD-L1 antibody + HER2 monoclonal antibody	Histologically confirmed adenocarcinoma of the breast with locally recurrent, unresectable disease or metastatic disease including: de novo metastatic diseas without prior history of HER2-positive BC or locally recurrent or metastatic disease following prior therapy for early BC	Open to accrual
Breast - Metastatic HER2-							
Parajuli	Mehta Coluzzi Nabar Nanci	Elizabeth Afu	Ana Gonzalez-Vargas	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	Elizabeth Afu	Dezurline Garcia	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	Elizabeth Afu	Dezurline Garcia	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
Parajuli	Nabar Mahdavi Mehta Nanci Coluzzi	Elizabeth Afu	Dezurline Garcia	UCI- 17-79: Single Arm, Open Label Phase 1b/2 Study of SGN-LIV1A in Combination with Pembrolizumab for First-Line Treatment of Patients with Unresectable Locally-Advanced or Metastatic Triple-Negative Breast Cancer	PD-1 /PD-L1 targeted	Metastatic triple negative breast cancer Have not previously received cytotoxic therapy for the treatment of unresectable LA/M BC. Treatment with agents other than hormonally-directed/endocrine therapies will be counted as regimens.	Open to Accrual
GU							
Hugen	Uchio Hugen	Elizabeth Afu	Alexander Gilbert	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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GI							
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Zell	Nabar Cho Jafari Neumann Dayyani Lee Carmichael	Elizabeth Afu	Kristian Ghio	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	Elizabeth Afu	Dorothy Chang	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
Carmichael	Elquza Jafari Lee Zell Cho shere Dayyani Mills	Elizabeth Afu	Elizabeth Afu	S1820: A Randomized Phase II Trial of the Altering Intake, Managing Symptoms (AIMS-RC) Intervention for Bowel Dysfunction in Rectal Cancer Survivors	Telephone Diet Modification Coaching (AIMS-RC) vs Telephone Health Education	Prior history of rectosigmoid colon or rectal cancer with post-surgical permanent ostomy or anastomosis. Last date of treatment for rectal cancer (surgery, chemo, RT) must be at least 6 months, but not more than 24 months prior to registration	Open to accrual
Dayyani	Lee Neumann Valerin Zell Cho Elquza	Elizabeth Afu	Kristian Ghio	UCI 18-124: Phase 2 Study of Cabozantinib Combined with Pembrolizumab in Metastatic Gastric and Gastroesophageal Adenocarcinoma	Cabozantinib and Pembrolizumab	•2nd or 3rd line treatment •Progression after at least one line of platinum FU-containing regimen	Open to accrual
Dayyani	Cho carmichael Elquza Jafari Lee Mills Nanci Neumann Valerin	Elizabeth Afu	Nicole Ferrand	UCI 20-03: BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer (CRC)	ctDNA-guided therapy after surgery	• Undergone surgery for stage II or III colorectal cancer with available tissue and whole blood samples •Using SIGNATERA test, may be recommended for adjuvant chemotherapy or observation by treating physician	Open to accrual
Dayyani	Cho Elquza Lee Zell Neumann Valerin	Elizabeth Afu	Nermene Wilson	UCI 20-63: A Phase IIa, Multicenter, Open-Label Study of DKN-01 in Combination with Tislelizumab ± Chemotherapy as First-Line or Second-Line Therapy in Adult Patients with Inoperable, Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (DisTinGuish)	DKN-01 + tislelizumab + CAPOX	• Part A will enroll G/GEJ adenocarcinoma patients who have received no prior systemic treatment in the locally advanced/metastatic setting (first-line treatment); exclusion: HER2-positive • Part B will enroll patients who received only 1 prior systemic treatment, which must consist of a platinum + fluoropyrimidine–based therapy (±HER2 therapy if applicable) for locally advanced/metastatic DKK1-high G/GEJ adenocarcinoma (second-line treatment)	Open to accrual

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GI							
Dayyani	Cho Coluzzi Lee Zell Valerin Mehta Neumann Parajuli Valerin	Elizabeth Afu	Baoan huynh	UCI 20-77: An Open-Label, Multi-Center Phase I/II Dose Escalation and Expansion Study to Assess the Safety, Efficacy and Pharmacokinetics of MRG002 in Patients with HER2-Positive Advanced Solid Tumors and Locally Advanced or Metastatic Gastric/Gastroesop	MRG002	•2nd or 3rd line treatment •Progression after at least one line of trastuzumab and/or platinum/fluorpyrimidine IHC 2-3+/ISH-positive HER2expression, OR • IHC 1+, or IHC 2+/ISH-negative HER2	Open to accrual
Dayyani	Abi-Joudeh Fernando Cho Imagawa Lee Jutric Neumann Valerin Wolf	Elizabeth Afu	Kristian Ghio	UCI 19-36: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Durvalumab Monotherapy or in Combination With Bevacizumab as Adjuvant Therapy in Patients With Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation (EMERALD-2)	Durvalumab: PD-L1 inhibitor; Bevacizumab: VEGF inhibitor	•HCC with completed curative therapy (resection or ablation) •Patients must be randomized within 12 weeks of completing curative therapy •Child-Pugh A5-A6	Open to accrual
Dayyani	Abi-jaoudeh Boyd Elquza Fernando Imagawa Jutric Katrivesis Lee Long neumann Valerin Zell Wolf	Elizabeth Afu	Kristian Ghio	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	Abi-jaoudeh Cho Imagawa Lee Neumann Soscia Valerin	Elizabeth Afu	Cindy Duong	UCI 20-79: A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients with Advanced Liver Cancers (Morpheus Liver)	Stage 1: Atezo/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
Dayyani	neumann zell	Elizabeth Afu	Jasmine Balangue	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	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 1.1	Open to accrual
Dayyani	Abi-Jaoudeh Cho Imagawa Jutric Lee Neumann Soscia Valerin Wolf	Elizabeth Afu	Kristian Ghio	UCI 19-70: A Phase Ib/II, Open-Label, Study of Tivozanib in Combination with Durvalumab in Subjects with Untreated Advanced Hepatocellular Carcinoma	Tivozanib, durvalumab	•1st line systemic treatment •Child Pugh A • Previous locoregional treatment: wash-out of 28 days prior to enrollment	Open to accrual

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GI							
Dayyani	Zell Cho Lee Valerin Neumann	Elizabeth Afu	Jasmine Balangue	UCI 20-134: Phase I study of Cabozantinib Plus TAS102 in mCRC as Salvage Therapy	Cabozatinib +TAS102	• Histologically or cytologically confirmed colorectal adenocarcinoma • Locally advanced, recurrent, or metastatic disease not amenable to curative surgery or radiation • Must have progressed, or not tolerated, a fluoropyrimidine, irinotecan, oxaliplatin, and cetuximab or panitumumab (only for RAS wild-type). Prior exposure to bevacizumab or ramucirumab is allowed. • Patients who have exhausted all other SOC options are also eligible	Open to accrual

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GI							
Dayyani	Nabar Cho Kalebasty Lee Mar Neumann Valerin Zell	Elizabeth Afu	Cindy Duong	UCI 19-119: Phase 1/1b Study to Evaluate the Safety and Activity of TTX-030 (Anti-CD39) in Combination with Budigalimab and/or Chemotherapy in Subjects with Advanced Solid Tumors	TTX-030 (anti-CD39) + Anti-PD-1 and/or mFOLFOX6	• Gastric: HER2-, chemotherapy-naïve • CRC (colorectal): microsatellite-stable, received up to 3 prior systemic chemotherapy regimens • RCC (renal): previously treated with up to 3 lines of prior therapies • HNSCC (head/neck): progression after checkpoint inhibitors • mCRPC (prostate): disease progression on recent prior systemic regimen, at least 2 prior systemic therapies	Open to accrual
Neuro							
Bota	Castillo Chow Hsu Myung Turner	Elizabeth Afu	Sherin Mathew	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	Elizabeth Afu	Elizabeth Chin	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
O'Brien	Nabar Nanci Mahdavi Pinter-Brown	Elizabeth Afu	Elizabeth Chin	A041702: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>/= 70 years of age) With Chronic Lymphocytic Leukeumia (CLL)	BTK + BCL2 + CD20 antibody	Must have newly diagnosed CLL to be eligible.	Open to accrual

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Correlative Trials							
Dayanni	Cho Lee ,J Neumann Samarasena Smith Valerin Zell	Elizabeth Afu	Jasmine Balangue	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
Basket Trials							
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Bota	Abi-Jaoudeh Nabar Lomax Cappauccini Ou Turner Valerin Zell	Elizabeth Afu	Daniel Sungchae Na	EAY131: Molecular Analysis for Therapy Choice	Treatment based on mutations	Positive for specific mutations	Open to accrual
Bota	Nabar Dayyani choi Fruehauf Lee Cappuccini Castillo Hsu Mehta Ou Pinter-Brown Turner Tseng Zell	Elizabeth Afu	Mehir Tharani	S1609: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	Immunotherapy	Recurrent disease - Rare cancer	Open to accrual

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Correlative/Non-Treatment Trial							
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	Coluzzi Lane Mehta Nanci Mahdavi Tsai	Elizabeth Afu	Ana Gonzalez-Vargas	UCI 17-43: Blood Collection Protocol for Circulating Tumor Cells and Circulating Cancer Associated Fibroblasts in Breast Cancer Patients	Blood Collection	Patients must be female, at least 21 years of age or older, with histolocially confirmed breast cancer and be diagnosed as Stage III or IV. Must not have other active cancers.	Open to accrual
Parajuli	Coffey-leis Kessenbrock Lane Mehta Police	Elizabeth Afu	Nicolas Ninofranco	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).	Open to accrual
Senthil	Dayyani Lee Zell Elquza Jakowatz neumann Mills Yamamoto	Elizabeth Afu	Baoan huynh	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 Mehta Nanci	Elizabeth Afu	Dezurline Garcia	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
Lin	Coluzzi Kansal Lane Mahdavi Mehta Nanci	Elizabeth Afu	Dezurline Garcia	S1904: Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ- Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)	Standard Educational Materials about Breast Cancer Risk/Chemoprevention + Web Based Decision Support Tools	Patients must have atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) with no history of invasive breast carcinoma or ductal carcinoma in situ (DCIS) No prior selective estrogen receptor modulators or aromatase inhibitor usage	Open to accrual
Supportive Care/Diagnostic							
PI	**Newport Sub-I**	**Newport CRC**	**CRC @ Orange**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Bota	Myung	Elizabeth Afu	Tharani Mehir	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

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