Neoadjuvant					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	Stephany Ruiz	UCI 21-185: A Phase 3 Open-label Trial of Neoadjuvant Trastuzumab Deruxtecan (T-DXd) Monotherapy or T-DXd followed by THP Compared to ddAC-THP in Participants with High-risk HER2-positive Early-stage Breast Cancer (DESTINY-Breast11)	HER2-targeting antibody drug conjugate	Locally assessed HER2-positive (IHC 3+ or ISH+) T0-4, N1-3, M0 or >T3, N0, M0	Open to Accrual
Yamamoto	Baoan Huynh	UCI 21-106: A Phase II Open-Label, Dose-Finding Study to Determine the Optimal Dose for Lymph Node Visualization Using ASP5354 in Participants with Breast Cancer or Melanoma Undergoing Sentinel Lymph Node Biopsy	Optical imaging agent	Female patients with localized breast cancer (Stage I/II, N0M0) No prior neoadjuvant chemotherapy No prior surgery/radiation to area of LN detection No definitive LN metastasis	Suspended
Adjuvant					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Healy	Stephany Ruiz	CCTG-MA39: Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer	Regional Radiotherapy	ER+, HER2- Women with newly diagnosed biomarker low risk node positive and T3N0 breast cancer with no evidence of metastases that have been treated by mastectomy or BCS. Oncotype DX recurrence score ≤ 25	Open to Accrual
Parajuli	Stephany Ruiz	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	Antibody drug conjugate + kinase inhibitor	Patients must have HER2+ breast cancer with residual disease after NACT No prior treatment w/ TDM-1	Open to Accrual
Parajuli	Stephany Ruiz	UCI 22-141 A Phase III Open-label, Randomized Study of Datopotamab Deruxtecan (Dato DXd) with or without Durvalumab Versus Investigator's Choice of Therapy in Patients with Stage I-III Triple-negative Breast Cancer who have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes Following Neoadjuvant Systemic Therapy and Surgical Resection	PDL-1 inhibitor	TNBC Completed at least 6 cycles of newadjuvant tx containing anthracycline and/or a taxane with or without carboplatin, with or without pembro No adjuvant systemic tx No known germline BRCA1 or BRCA2 mutation	Open to Accrual
Mehta	Stephany Ruiz	NRG-BR007: A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer	radiation therapy versus no radiation therapy + Endocrine therapy	Patients with resected pT1N0M0, HER2-Negative, ER and/or PR-Positive Breast Cancer and Oncotype-DX Recurrence Score ≤ 18	Open to Accrual
Metastatic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	Alexis Chavez	UCI 22-114: A Phase III, Randomized, Open-label, Multicenter Study Evaluating the Efficacy and Safety of Giredestrant Plus Everolimus Compared with Exemestane Plus Everlimus in Patients with Estrogen Receptor-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer	Proteasome-mediated degradation	Prior ET with CDK4/6i (metastatic: disease progression >6 months after initiation ET + CDK) (adjuvant: relapse while taking or within 12 months of exposure to combo adjuvant ET and CDK)	Open to Accrual
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)	Must have histologically confirmed TNBC (ER and PR ≤10%, HER2-negative per ASCO/CAP guidelines) that is metastatic or unresectable.	Open to Accrual

Parajuli	Stephany Ruiz	UCI 22-222: A Phase III, Mutlicenter, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Inavolisib Plus Fulvestrant versus Alpelisib Plus Fulvestrant in Patients with Hormone Receptor-Positive, HER2-Negative, PIK3CA Mutated, Locally Advanced or Metastatic Breast Cancer Who Progressed During or After CDK4/6 Inhibitor and Endocrine Combination Therapy	PI3K inhibitor	Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to surgical or radiation therapy with curative intent HR +, HER2- (HER2 immunohistochemistry (IHC) score of 0 or 1 +, or HER2 IHC score of 2 +) Disease progression after or during treatment with a combination of CDK4/6i and ET (must have received no more than two prior lines of systemic therapy in the locally advanced (recurrent or progressed) or metastatic setting)	Open to Accrual

Parajuli	TBD	UCI 22-139: A Phase 3, Open-Label, Randomized, Two-Part Study Comparing Gedatolisib in Combination with Palbociclib and Fulvestrant to Standard-of-Care Therapies in Patients with HR-Positive, HER2-Negative Advanced Breast Cancer Previously Treated with a CDK4/6 Inhibitor in Combination with Non-Steroidal Aromatase Inhibitor Therapy (VIKTORIA-1)	PI3K/mTOR inhibitor	ER+/PR+, Progressed during or after CDK4/6 inhibitor combination treatment with non-steroidal aromatase inhibitor (AI) At least 2 weeks beyond treatment with a targeted therapy or major surgery and at least 3 weeks beyond immunotherapy and/or radiation therapy	Open to Accrual
Mehta	Stephany Ruiz	UCI 19-145 A Phase II, Open-Labeled, Single-Armed Combination Treatment with Anastrozole, Fulvestrant and Abemaciclib for Hormone Receptor Positive, HER2(-) Metastatic Breast Cancer	CDK 4/6 inhibitor+ER Regulator+Aromatase Inhibitor	Breast cancer with ER+ or PR+Her2-. Exclude HER2+ or TNBC, received (neo)adjuvant endocrine or chemotherapy <12 months before. No prior treatment with CDK4/6 inhibitor and/or fulvestrant	Open to Accrual
Parajuli	Stephany Ruiz	UCI 21-212: A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1	Antibody drug conjugate	Patients with locally advanced inoperable or metastatic TNBC who have not received previous systemic therapy for advanced disease and whose tumors are PD-L1 positive at screening Must have completed treatment for Stage I to III breast cancer, if indicated, and ≥ 6 months must have elapsed between completion of treatment with curative intent	Open to Accrual
Parajuli	Alexis Chavez	UCI 22-09: A Phase Ib, First-In-Human, Dose Escalation and Expansion, Multicenter Study of XMT-1660 in Participants with Solid Tumors Likely to Express B7-H4	Antibody drug conjugate	Metastatic TNBC, HR+/HER2- breast cancer, or endometrial cancer, or ovarian, fallopian tube, or primary peritoneal cancer. For HR+/HER2- patients must have received at least one line of systemic therapy which must have included CDK 4/6 inhibitor + endocrine therapy (ET), in an advanced or metastatic setting For TNBC must have received at least 2 lines of systemic therapy in locally advanced or metastatic BC setting.	Open to Accrual
Parajuli	Alexis Chavez	ETCTN 10302: Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer	Bone-targeted alpha particle emitting radiopharmaceutical	HER2-, metastatic breast cancer If HR+, disease should have progressed on at least one line of hormone therapy and a CDK 4/6 inhibitor in metastatic setting No prior therapy w/ radionuclides	Open to Accrual
Parajuli	Alexis Chavez	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 (FAC vs FA)	Pan-class I PI3K inhibitor	HR+/HER2- metastatic breast cancer No more than one chemotherapy line in metastatic setting For patients enrolling on Phase 2 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	Suspended
Parajuli	Alexis Chavez	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

Parajuli	Alexis Chavez	UCI 21-57: A Phase Ib/II, 2-Part, Open-Label Study to Assess the Safety and Antitumor Activity of Zanidatamab in Combination with ALX148 in Advanced HER2-Expressing Cancer	IgG1-like antibody + CD47 inhibitor	Locally advanced or metastatic HER2-positive or HER2-low (IHC1+/IHC2+, HER2-negative) breast cancer. Must have progression during or after the most recent treatment for advanced/metastatic cancer. No prior treatment with anti-CD47 or SIRP-alpha agent. If brain metastasis is present, disease must be stable. For HER2-low subjects, no prior HER2-targeted therapy is allowed. PART 2 DOSE EXPANSION COHORTS: Cohort 1 HER2+; Cohort 2 HER2-LOW	Open to Accrual
Parajuli	TBD	UCI 21-82: A Phase I/II, Open Label, Dose-Escalation Study of Oral ORIN1001 With and Without Chemotherapy in the Treatment of Subjects with Solid Tumors	XBP1-splicing inhibitor	Phase I: Relapsed refractory metastatic breast cancer (TNBC or ER+/HER2-) w/ advanced solid tumors. Must have progressed on at least 2 lines of therapy. Cohort C2A: 300 mg + Abraxane combo Phase II: no more than three lines of systemic therapy in the metastatic setting. Cohort A-TNBC, Cohort B-MYC+, Cohort C-ER+/HER2-, Cohort D-TNBC	Suspended

Solid Tumors/Basket Trials					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Choi	Daniel Na	Alliance A071701: Genetic Testing in Guiding Treatment for Patients with Brain Metastases	CDK inhibitor + PI3K inhibitor + NTRK/ROS1 inhibitor	Histologically confirmed metastatic disease to the brain from any solid tumor. If progression occurred for the following tx in the metastatic setting: for HER2-positive breast cancer received prior HER-2 directed therapy; for TNBC, at least one chemotherapy in metastatic setting	Open to Accrual
Kalebasty	Madina Popal	UCI 20-179: A Phase I/IB First-in-Human Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Patients with Advanced Solid Tumors	SHP2 inhibitor	Patients must have a metastatic solid tumor with MAPK-pathway alterations (excluding BRAF V600x) and no avaialble SOC therapies Patients with tumors harboring known activating mutations in BRAF V600X or SHP2 will be excluded Patients must not have previously received a SHP2 inhibitor	Open to Accrual
Ou	Richard Chang	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	mTOR inhibitor	Advanced solid tumors that have failed, are intolerant to, or are considered ineligible for SOC anticancer treatments No prior mTOR and/or PI3K inhibitors	Open to Accrual
Nagasaka	Jenny Choe	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
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	Immunotherapy agent targeting NK cells.	Locally advanced or metastatic solid tumors w/ HER2 expression by immunohistochemistry and/or erbb2 amplification and/or erbb2 activating mutations must be documented on either archival tissue or fresh tumor biopsy.	Open to Accrual
Nagasaka	Celest Ramirez	UCI 21-161: A Phase I/II Dose Escalation and Dose Expansion Study of BA3021 Alone and in Combination with Nivolumab in Patients with Advanced Solid Tumors	ROR2 Monoclonal Antibody	Advanced unresectable or metastatic solid tumors that have failed all SoC Therapy. ROR2-positive disease determined by IHC	Open to Accrual

Parajuli	TBD	UCI 21-82: A Phase I/II, Open Label, Dose-Escalation Study of Oral ORIN1001 With and Without Chemotherapy in the Treatment of Subjects with Solid Tumors	XBP1-splicing inhibitor	Phase I: Males or females with advanced solid tumors for which no effective standard of care treatments are available. Cohort 5: 500 mg Single Agent	Suspended
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	Antibody drug conjugate	Stage III or IV locally advanced or metastatic NSCLC, breast cancer, or ovarian cancer, or any stage recurrent disease Must be receiving cancer treatment with carboplatinum-based combination chemotherapy regimens Must have a platelet count < 75 x 109/L	Open to Accrual

Non-Treatment Trials (Diagnostic/Screening/Basic Science)					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	Billy Sanchez	UCI 17-05: Understanding Intratumoral Heterogeneity Using Single Cell RNA Sequencing	RNAseq	Patients with or without cancer who undergo prophylactic mastectomy, reduction mammoplasty or lumpectomy. Patients (stage I-IV) irrespective of the Hormonal or Her-2 receptor and BRCA status who will undergo breast or axillary node biopsy, definite surgery or prophylactic surgery	Open to Accrual
Chan	Matthew Heshmatipour	UCI 21-33: Electroacupuncture for the Management of Complex Symptoms in Cancer Patients and Survivors: A Feasibility Study	Electroacupuncture	Patients with Stage I-III solid tumors, except CNS tumors Patients with metastasis, psychiatric or mental disorders, needle phobia, bleeding disorders, or have already received acupuncture treatment in the past 3 months will be excluded.	Open to Accrual
Anton-Culver	TBD	UCI 16-23: Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer [The WISDOM study (Women Informed to Screen Depending on Measures of Risk)]	Risk based screening strategy	Patients must be between the ages of 40 to 74 years old. Patients must agree to receive breast screening at an Athena site (UCSF, UCSD, UCLA, UCI, or Stanford).	Open to Accrual
Daroui	TBD	UCI 13-19: Registry Study of Patients Treated with Neoadjuvant Chemotherapy Followed by Mastectomy in Stage I, II, III Breast Cancer	Data Collection	Patients treated with chemotherapy followed by Mastectomy	Open to Accrual
Parajuli	Alexis Chavez	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
Bristow	TBD	UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California	Baseline Assessment	Patients must be at least 18 years of age and diagnosed with breast cancer	Pending Activation

Aalvarez 509-6084/Sruiz 509-2698
CColmenares 509-2172/NTharani 509-369
KMueller 509-2369/BHuynh 509-6233
AAguilar 509-2431/CRamirez 509-2738
DNa 509-2759/Achavez 509-2442