# Breast-Oncology Clinical Trials

## Neoadjuvant

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mehta</td>
<td>Ashley Chanthapadth</td>
<td>UCI 14-67: A Phase II Study of Breast Cancer Treatment Using Weekly Carboplatin + Paclitaxel + Trastuzumab (HER2+) in the Neoadjuvant Setting</td>
<td>HER-2 monoclonal antibody VEGF monoclonal antibody</td>
<td>Pathologically proven invasive breast cancer Tumor size is clinically at least 1 cm in greatest diameter (palpable or by imaging) and/or with involved lymph node</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Mehta</td>
<td>Ashley Chanthapadth</td>
<td>SI1418: A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with &gt; 1 cm Residual Invasive Cancer or Positive Lymph Nodes (&gt;pN1mic) After Neoadjuvant Chemotherapy</td>
<td>anti-PD-1 inhibitor (immunotherapy)</td>
<td>Patients must have triple negative cancer with &gt;1cm residual invasive cancer or positive lymph nodes after neoadjuvant chemotherapy No prior immunotherapy with anti-PD-L1, anti-PD-1, anti-CTLA4, or similar drugs</td>
<td>Open to Accrual</td>
</tr>
</tbody>
</table>

## Adjuvant

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuo</td>
<td>Ashley Chanthapadth</td>
<td>Alliance A221505: Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction</td>
<td>fractionated external radiation therapy</td>
<td>Patients must have undergone immediate reconstruction at the time of mastectomy or be planning to undergo reconstruction within 8 months after radiation</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Mehta</td>
<td>Ashley Chanthapadth</td>
<td>UCI 18-79: A Phase II Clinical Trial on Neo-Adjuvant Abemaciclib with Fulvestrant in Patients with ER/PR + HER-2 Negative Breast Cancer who Developed Localized Recurrence While on Adjuvant Endocrine Therapy with Molecular Evidence of Endocrine Resistance</td>
<td>CXD Inhibitor + Neoadjuvant Endocrine Therapy</td>
<td>Post-menopausal female patients Histologically confirmed ER+ Breast Cancer Patients must have localized recurrence while on adjuvant endocrine therapy Patients must not have inflammatory breast cancer No prior treatment with any CDK 4/6 inhibitor and/or Fulvestrant</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>UCI 20-60 A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination with Abemaciclib to Patients with ER+, HER2- Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers</td>
<td>non-covalent oral SERD</td>
<td>Locally advanced unresectable or metastatic ER+, HER2- breast cancer or endometrial cancer. Up to 3 lines of treatment in advanced/metastatic setting and progression while on endocrine therapy.</td>
<td>Pending Activation</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>UCI 19-66: Randomized, Double-Blind, Phase III Study of Tucatinib or Placebo in Combination with Ado-Trastuzumab Emtansine (T-DM1) for Subjects with Unresectable Locally-Advanced or Metastatic HER2+ Breast Cancer</td>
<td>resistance to antibody-mediated inhibition using tyrosine kinase inhibitor and antibody-based therapy</td>
<td>Patients must have history of prior treatment with a taxane and trastuzumab in any setting, separately or in combination. Prior pertuzumab therapy is allowed, but not required. No prior treatment with tucatinib, lapatinib, neratinib, zafitabir, trastuzumab deruxtecan (DS-8201a), or any other investigational anti-HER2, anti-EGFR, or HER2 TKI agent or T-DM1.</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>UICG-8004: A Randomized, Double-Blind, Phase III Trial of Pertuzumab/Trastuzumab/Pertuzumab with Tucatinib or Placebo in First-Line HER2-Positive Metastatic Breast Cancer</td>
<td>PD-L1 antibody + HER2 monoclonal antibody</td>
<td>Histologically confirmed adenocarcinoma of the breast with locally recurrent, unresectable disease or metastatic disease including: de novo metastatic disease without prior history of HER2-positive BC or locally recurrent or metastatic disease following prior therapy for early BC</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Coluzzi</td>
<td>Linda Vo</td>
<td>UCI 19-88: A Phase III Double-Blind Randomised Study Assessing the Efficacy and Safety of Capivasertib + Fulvestrant versus Placebo + Fulvestrant as Treatment for Locally Advanced (Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth</td>
<td>AKT inhibitor + selective estrogen down-regulator</td>
<td>HR+/HER2- breast cancer with progression on an AI No more than 1 line of chemotherapy or more than 2 lines of endocrine therapy in the metastatic setting No prior treatment with Fulvestrant or AKT/Pi3K/mTOR inhibitors</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>UCI 17-79: Phase 1b/2 study of SGN-LV1A in combination with pembrolizumab for first-line treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer</td>
<td>IgG1 monoclonal antibody binding to LIV-1 and linker in lysosomes releasing MMAE which prevents cell division.</td>
<td>Metastatic or locally-advanced triple-negative breast cancer Have not previously received therapy for the treatment</td>
<td>Open to Accrual</td>
</tr>
</tbody>
</table>

## Metastatic

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI</td>
<td>CRC</td>
<td>Protocol #/Title</td>
<td>Mechanism</td>
<td>Primary In/Ex Criteria</td>
<td>Status</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Bota</td>
<td>Mehir Tharani</td>
<td>Alliance A071701: Genetic Testing in Guiding Treatment for Patients with Brain Metastases</td>
<td>CDK inhibitor + PI3K inhibitor + NTRK/ROS1 inhibitor</td>
<td>Histologically confirmed metastatic disease to the brain from any solid tumor. If progression occurred for the following tx. For HER2-positive breast cancer received prior HER-2 directed therapy; for TNBC, at least one chemotherapy.</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>ECTTN 10302: Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer</td>
<td>Bone-targeted alpha particle emitting radiopharmaceutical</td>
<td>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.</td>
<td>Pending Activation</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>ECTTN 10287: A Randomized Phase I/I 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)</td>
<td>Pan-class I PI3K inhibitor</td>
<td>HR+/HER2- metastatic breast cancer. 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</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Parajuli</td>
<td>Linda Vo</td>
<td>UCI 18-43: A Phase 1 First in Human Study Evaluating Safety and Efficacy of ABBV-155 Monotherapy and Combined with Docetaxel in Adult Patients with Relapsed and Refractory Solid Tumors</td>
<td>Antibody drug conjugate</td>
<td>Failure of at least 1 systemic chemotherapy for subjects in Part 1A and 1B (dose escalation). Subjects enrolled in Part 2a (monotherapy, dose expansion) must have SCC with tumors that express B7H3 above a given threshold per central laboratory testing; Subjects enrolled in Part 2b (combination therapy, dose expansion) must have either NSCLC or HR+/HER2- breast cancer with tumors that express B7H3 above a given threshold per central laboratory testing and must have failed CDK 4/6 therapy.</td>
<td>Open to Accrual</td>
</tr>
</tbody>
</table>

### Solid Tumors/Basket Trials

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bota</td>
<td>Celine Colmenares</td>
<td>UCI 18-38: A Phase I/II, Open-Label First-in-Human Study of the Safety, Tolerability, and Feasibility of Gene-Edited Autologous NeoTCT-R Cells (NeoTCT-P1) Administered as a Single Agent or in Combination with Anti-PD-1 to Patients with Locally Advanced or Metastatic Solid Tumors</td>
<td>Autologous adoptive T-cell therapy + Anti-PD-1</td>
<td>Patients willing to undergo a leukapheresis procedure. Patients with histologically or cytologically documented incurable metastatic ER+/HER2(+) breast cancer. Patients who have ≥2 endocrine therapies for treatment of advanced/MBC (one of which was in combination with a CDK 4/6 inhibitor). Patients who have received ≥1 chemotherapy regimen for the treatment of advanced/MBC.</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Bota</td>
<td>Ricardo Avalos</td>
<td>ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)</td>
<td>Mutation based treatment</td>
<td>Positive for Specific Mutations</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Ou</td>
<td>Anabel Serwanska</td>
<td>UCI 18-21: A Phase I/I 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)</td>
<td>RET Receptor Tyrosine Kinase inhibitor that harbors RET alterations</td>
<td>Patient with RET fusion-positive solid tumor or an advanced solid tumor that harbors a RET gene alteration (excluding synonymous, frameshift, or nonsense mutation).</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Valerin</td>
<td>Kristian Ghio</td>
<td>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</td>
<td>Immunotherapy agent targeting NK cells.</td>
<td>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.</td>
<td>Pending Activation</td>
</tr>
</tbody>
</table>

### Non-Treatment Trials (Diagnostic/Screening/Basic Science)

<table>
<thead>
<tr>
<th>PI</th>
<th>CRC</th>
<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anton-Culver</td>
<td>Andrea Alvarez</td>
<td>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])</td>
<td>Risk based screening strategy</td>
<td>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).</td>
<td>Open to Accrual</td>
</tr>
<tr>
<td>Investigator</td>
<td>Contact Info</td>
<td>Trial Title</td>
<td>Objectives</td>
<td>Status</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>-------------</td>
<td>------------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>Kuo Bianca Del Vecchio</td>
<td>Linda Vo x456-62640/Ashley Chanthapadith x509-2925/Anabel Serwanska x456-8279/Ricardo Avalos x509-2495/Celine Colmenares x509-2172/Kristian Ghio x456-6285/Mehir Tharani x509-2643</td>
<td>UCI 13-19: Registry Study of Patients Treated with Neoadjuvant Chemotherapy Followed by Mastectomy in Stage I, II, III Breast Cancer</td>
<td>Data Collection; Patients treated with chemotherapy followed by Mastectomy</td>
<td>Open to Accrual</td>
<td></td>
</tr>
<tr>
<td>Uchio Nyles Oune</td>
<td>Linda Vo/Parajuli Ashley Chanthapadith</td>
<td>UCI 18-103: Blood Sample Collection to Evaluate Biomarkers in Subjects with Untreated Solid Tumors</td>
<td>Blood Collection; Patient has an untreated primary malignancy of breast</td>
<td>Open to Accrual</td>
<td></td>
</tr>
<tr>
<td>Parajuli Linda Vo/Chanthapadith</td>
<td>Linda Vo</td>
<td>UCI 18-136: Blood Collection Protocol for the Analysis of Exosomes in Patients with Breast Cancer</td>
<td>Blood Collection; Patient with Stage I, Stage II, Stage III and Stage IV Breast cancer Hormone Receptor+, Her-2 receptor positive, triple positive or triple negative breast cancer</td>
<td>Pending Activation</td>
<td></td>
</tr>
<tr>
<td>Bristow TBD</td>
<td>TBD</td>
<td>UCI 19-25: Baseline Assessment of Cancer Health Disparities in Underserved Populations in California</td>
<td>N/A; Patients must be at least 18 years of age and diagnosed with breast cancer</td>
<td>Pending Activation</td>
<td></td>
</tr>
<tr>
<td>Parajuli Linda Vo</td>
<td>Linda Vo</td>
<td>UCI 17-43: Blood Collection Protocol for Circulating Tumor Cells and Circulating Cancer Associated Fibroblasts in Breast Cancer Patients</td>
<td>Blood Collection; Patients must be female, at least 21 years of age or older, with histologically confirmed breast cancer and be diagnosed as Stage III or IV, Must not have other active cancers.</td>
<td>Open to Accrual</td>
<td></td>
</tr>
<tr>
<td>Tanjasiri TBD</td>
<td>Carmen Lam (Orange) Marlisse Holbrook (Newport)</td>
<td>UCI 19-101: Cancer Navigation for Vietnamese Americans (CANVAS)</td>
<td>Data Collection; Patients must be female, Vietnamese or Vietnamese American, at least 21 years of age or older, and in the early phases of their breast cancer experiences (ideally before or immediately after surgery) of invasive breast cancer stages I-III</td>
<td>Pending Activation</td>
<td></td>
</tr>
<tr>
<td>O’Brien TBD</td>
<td>Carmen Lam (Orange) Marlisse Holbrook (Newport)</td>
<td>NCICCOVID: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study</td>
<td>Data Collection; Blood and Imaging; Positive SARS CoV-2 test within the 14 days Currently undergoing treatment for cancer (including chemotherapy, immunotherapy, monoclonal antibody therapy, target therapy, endocrine therapy, radiation therapy) or has received a transplant as cancer treatment</td>
<td>Open to Accrual</td>
<td></td>
</tr>
</tbody>
</table>