

Breast Disease-Oriented Team

Clinical Research Treatment Trial Flowchart



■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

Neoadjuvant Therapy

HER2+

NRG-BR008 (Any HR)

Arm 1: RT + cont. HER2-targeted therapy + HR therapy per investigator discretion
Arm 2: No RT + cont. HER2-targeted therapy + HR therapy per investigator discretion

PI: Healy
Coord: Paula Cabanting
Accrual: 0/5

HER2-

SWOG S2206 (HER2- /low/equivocal)

Arm 1: SOC AC-T
Arm 2: SOC AC-T + Durvalumab (IgG1k mAb) MammaPrint Index Score MP2 required

PI: Parajuli
Coord: Paula Cabanting
Accrual: 0/10

TNBC

UCI 23-124 (HR-low)

Neoadjuvant Dato-DXd (ADC) + durvalumab → surgery → adjuvant durvalumab +/- chemo

Neoadjuvant pembrolizumab + carboplatin + paclitaxel → pembrolizumab + doxorubicin or epirubicin + cyclophosphamide → surgery → adjuvant pembrolizumab +/- chemo

PI: Parajuli
Coord: TBD
Accrual: 0/5



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HR+, HER2-

HER2+

TNBC

UCI 22-111
 Arm A: Imlunestrant PO (ER antagonist/degrader)
 Arm B: Investigator's choice ET
 Tamoxifen or AI

PI: Parajuli
 Coord: Stephany Ruiz/Helen Tam
 Accrual: 1/5

NRG BR008 (Any HR)
 Arm 1: RT + cont. HER2-targeted therapy + HR therapy per investigator discretion
 Arm 2: Cont. HER2-targeted therapy + HR therapy per investigator discretion

PI: Healy
 Coord: Paula Cabanting
 Accrual: 0/5

UCI 22-141
 Arm 1: Dato-DXd (ADC) IV + Durva IV
 Arm 2: Dato-DXd IV
 Arm 3: Investigator's choice (capecitabine, pembro, or capecitabine + pembro)

PI: Parajuli
 Coord: Juan Miranda
 Accrual: 1/5

NRG BR007
 Arm 1: RT + ET
 Arm 2: ET
 Oncotype-DX Recurrence Score ≤ 18 (unless T1a tumor) required

PI: Mehta
 Coord: Paula Cabanting
 Accrual: 1/5

ALLIANCE A011801 (Any HR)
 Antibody drug conjugate + kinase inhibitor

PI: Parajuli
 Coord: Alexis Chavez
 Accrual: 4/5

ALLIANCE A012103
 Arm 1: Pembrolizumab IV
 Arm 2: Observation

PI: Parajuli
 Coord: Juan Miranda
 Accrual: 0/5



1L

UCI 19-145

Abemaciclib (CDK 4/6 inhibitor) + Fulvestrant (ER antagonist) + Anastrozole (AI)

PI: Mehta

Coord: Stephany Ruiz/Paula Cabanting

Accrual: 11/20



2L+

UCI 22-114 (1-3L)

Giredestrant (Proteasome-mediated degradation) +
Everolimus (mTOR inhibitor)
Physician's choice of ET

PI: Parajuli
Coord: Alexis Chavez
Accrual: 3/5

UCI 22-139 (VIKTORIA-1) (2-3L)

PIK3CA WT: Arm A: Gedatolisib (PI3K/mTOR inhibitor) +
Palbociclib + Fulvestrant; Arm B: Gedatolisib + Fulvestrant; Arm
C: Fulvestrant (+ optional crossover)
PIK3CA Mutant: Arm D: Gedatolisib + Palbociclib + Fulvestrant;
Arm E: Alpelisib + Fulvestrant; Arm F: Gedatolisib + Fulvestrant

PI: Parajuli
Coord: Alexis Chavez
Accrual: 3/5

UCI 22-222 (INAVO121)

PIK3CA Mutant
Arm 1: Inavolisib (PI3K α isoform inhibitor) + Fulvestrant
Arm 2: Alpelisib + Fulvestrant

PI: Parajuli
Coord: Stephany Ruiz
Accrual: 0/4

UCI 22-09 (TNBC, HR+/HER2-)

Antibody drug conjugate
SLOT RSVP REQ

PI: Parajuli
Coord: Juan Miranda
Accrual: 2/5



2L+

Metastatic: HER2 Low, HER2+

UCI 24-49 (HER2+ IHC 2-3+, HER2 Amp ISH)

Dose Esc (Ph Ib):

Cohort A: Zongertinib (BI 1810631; HER2 inhibitor) + T-DM1

Cohort B: BI 1810631 + T-DXd

Dose Optimization (Ph II):

Cohort D: BI 1810631 + T-DM1

Cohort E: BI 1810631 + T-DXd

PI: Dayyani
 Coord: TBD
 Accrual: 0/10

ETCTN 10358 (DASH) (HER2 IHC 1-3+ or HER2 Amp ISH/NGS)

DS8201a + AZD6738

PI: Dayyani
 Coord: My Nguyen
 Accrual: 0/3

UCI 23-177 (HER2 IHC 1+, IHC 2+/ISH-)

Arm 1: DB-1303 (ADC)

Arm 2: Physician's choice (capecitabine, paclitaxel, nab-paclitaxel)

PI: Mehta
 Coord: TBD
 Accrual: 0/5

UCI 23-109 (HER2 IHC ≥1+)

Cohort A: HER2-Low: Disitamab Vedotin (ADC) vs. DV + Tucatinib

Cohort B: HER2+: DV vs. DV + Tucatinib

SLOT RSVP REQ (Dose Esc)

PI: Dr. Dayyani

Coord: My Nguyen/Juan Miranda
 Accrual: 1/10



METASTATIC: 1L+

UCI 21-212 (ASCENT-04)

Arm A: Pembrolizumab + Sacitizumab Govitecan (ADC)
 Arm B: Pembrolizumab + Chemotherapy (physician choice)
 PD-L1+

PI: Parajuli
 Coord: Alexis Chavez
 Accrual: 0/3

ETCTN 10546

ASTX727 (Cytidine deaminase (CDA) inhibitor + nucleoside
 hypomethylating agent (HMA)) + Paclitaxel +
 Pembrolizumab
SLOT RSVP REQ

PI: Parajuli
 Coord: Alexis Chavez
 Accrual: 1/5

UCI 22-09 (TNBC, HR+/HER2-)

XMT-1660 (ADC) – BC, EC, OC, ACC-I
 Dose Esc, Backfill Cohort, Exp
SLOT RSVP REQ

PI: Parajuli
 Coord: Juan Miranda
 Accrual: 2/5



ALL

UCI 23-07

P-MUC1C-ALLO1 cell infusion – breast, ovarian, NSCLC, CRC, pancreatic, other epithelial-derived cancers

SLOT RSVP REQ

PI: Mehta
Coord: Juan Miranda/Helen Tam
Accrual: 0/5

UCI 22-156

Tumor infiltrating lymphocyte therapy – breast, CRC, uveal melanoma, cutaneous melanoma, NSCLC, HNSCC

SLOT RSVP REQ

PI: Parajuli
Coord: Juan Miranda
Accrual: 0/5

FOR NEUROPATHY

ALLIANCE A222101

Ganglioside-Monosialic Acid (GM1)
To prevent paclitaxel-associated neuropathy

SLOT RSVP REQ

PI: Parajuli
Coord: Alexis Chavez
Accrual: 0/30



BASIC SCIENCE

UCI 18-136

PI: Parajuli
Coord: Billy Joel Sanchez/Caylee Carlton
Accrual: 66/100

UCI 17-05 (BRCA1 -/-, +/-)

PI: Parajuli
Coord: Billy Joel Sanchez
Accrual: 48/75

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SUPPORTIVE CARE

UCI 24-64

High fiber diet as therapy response and reduce recurrence

PI: Whiteson
Coord: TBD
Accrual: 0/60

HEALTH SERVICES RESEARCH

UCI 24-28

PI: Sadigh
Coord: TBD
Accrual: 0/90