

Breast Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

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: Stephany Ruiz
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: 2/10

UCI 23-132 (ISPY2)

S1: HR+HER2-Immune-DRD-
S2: HR-HER2-Immune-DRD-
S3: HER2-Immune+
S4: HER2-Immune-DRD+
S5: HER2+HER2 or Basal
S6: HER2+ Luminal

PI: Lavasani
Coord: TBD
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: Juan Miranda

Accrual: 0/5

HR+

UCI 22-111

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

PI: Parajuli
 Coord: Stephany Ruiz/Juan Miranda
 Accrual: 4/15

NRG BR009

Arm 1: Ovarian Function Suppression + AI
 Arm 2: Adjuvant Chemotherapy + Ovarian Function
 Suppression + AI
 Oncotype-DX Recurrence Score \leq 18 (unless T1a tumor)
 required

PI: Parajuli
 Coord: TBD
 Accrual: 0/5

NRG BR007

Arm 1: RT + ET
 Arm 2: ET
 Oncotype-DX Recurrence Score \leq 18 (unless T1a tumor)
 required

PI: Mehta
 Coord: Stephany Ruiz
 Accrual: 1/5

HER2+

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: Stephany Ruiz

Accrual: 0/5

ALLIANCE A011801 (CompassHER2) (Any HR)

Antibody drug conjugate +
kinase inhibitor

PI: Parajuli

Coord: Stephany Ruiz

Accrual: 4/10

TNBC

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)

SLOT RSVP REQ

PI: Parajuli

Coord: Alexis Chavez

Accrual: 1/5

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: 16/20

2L+

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

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

2L+

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

23-109 (HER2 IHC $\geq 1+$)

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: 2/10

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

Arm 1: DB-1303 (ADC)

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

PI: Mehta

Coord: Juan Miranda

Accrual: 1/5

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

UCI 21-40

Ph 1 Dose Esc: DF6002 (IL12-Fc fusion protein) monotherapy
 Ph 1b Dose Esc + Safety PK/PD Exp: DF6002 + nivolumab
SLOT RSVP REQ

PI: Valerin
 CRC: Bao Huynh/TBD
 Accrual: 5/10

UCI 24-08
SPEDOX-6 IV

PI: Chow
 Coord: TBD
 Accrual: 0/50

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
Accrual: 0/5

UCI 22-171

Part 1 Dose Esc + Safety PK/PD and Part 2 Exp: DF6215 monotherapy (IL-2-Fc C-terminus fusion protein)

SLOT RSVP REQ

PI: Valerin
CRC: My Nguyen/TBD
Accrual: 4/25

UCI 22-156

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

SLOT RSVP REQ – notify CRC to check slots despite “suspension”

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

UCI 23-197

Part 1 Dose Esc + Safety PK/PD and Part 2 Exp: DF6215 monotherapy (IL-2-Fc C-terminus fusion protein)

SLOT RSVP REQ

PI: Valerin
CRC: Natalie Arechiga/TBD
Accrual: 1/5

ALL

UCI 24-65

FMC-376 (KRAS G12C inhibitor) PO
Cohort 1A Dose Esc
Cohort 1B Dose Exp
Ph 2 Cohort Exp

PI: Dayyani
Coord: TBD

UCI 24-82

NEW: Study of IK-595, an ORAL dual MEK/RAF inhibitor in patients with RAS- or RAF- advanced solid tumors
SLOT RSVP REQ

PI: Valerin
Coord: Nicole Ferrand
Accrual: 0/10

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: 72/100

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

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

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: 29/90