

Breast Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

HER2+

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

COGNITIVE IMPAIRMENT

UCI 24-05

Riluzole PO vs. placebo PO
Perceived worsening of cognitive function

PI: Chan
Coord: Randy Kang
Accrual: 0/26

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 ≤ 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 ≤ 18 (unless T1a tumor)
 required

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

HER2+

ALLIANCE A011801 (CompassHER2) (Any HR)

Antibody drug conjugate +
kinase inhibitor

PI: Parajuli
Coord: Stephany Ruiz
Accrual: 4/10

TNBC

ALLIANCE A012103

Arm 1: Pembrolizumab IV

Arm 2: Observation

PI: Parajuli

Coord: Juan Miranda

Accrual: 0/5

COGNITIVE IMPAIRMENT

UCI 24-05

Riluzole PO vs. placebo PO
Perceived worsening of cognitive function

PI: Chan
Coord: Randy Kang
Accrual: 0/26

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

UCI 23-146

Unresectable or Mets HER2-low or HER2- with T-DXd

HR+ (Cohort 1: HER2-low vs Cohort 2: HER2-)

HR- (Cohort 3: HER2-low vs Cohort 4: HER2-)

PI: Parajuli

CRC: TBD

Accrual: 0/5

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 ≥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: Alexis Chavez/Randy Kang

Accrual: 1/5

UCI 23-146

Unresectable or Mets HER2-low or HER2- with T-DXd

HR+ (Cohort 1: HER2-low vs Cohort 2: HER2-)

HR- (Cohort 3: HER2-low vs Cohort 4: HER2-)

PI: Parajuli

CRC: TBD

Accrual: 0/5

METASTATIC: 1L+

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

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 24-08

SPEDOX-6 IV

PI: Chow

Coord: TBD

Accrual: 0/50

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

ALL

UCI 22-171 (EGFR Mutation)

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 24-142

Phase 1 Dose Esc

Group A: VET3-TGI monotherapy by ITu injection

Group C: VET3-TGI monotherapy by IV infusion

Group B: VET3-TGI by ITu injection, Group D: VET3-TGI IV infusion combo with pembrolizumab

PI: Uchio

CRC: Phil Duffy/TBD

Accrual: 0/4

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 22-26

(Androgen and glucocorticoid receptor antagonist) BRAF mutant. *temp hold on screening*

HPB/Panc Coord: Miranda Duron

Breast Coord: TBD

PI: Dr. Dayyani
 Accrual: 10/12

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

NEUROPATHY

ALLIANCE A222101

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

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

COGNITIVE IMPAIRMENT

UCI 24-05

Riluzole PO vs. placebo PO
Perceived worsening of cognitive function

PI: Chan
Coord: Randy Kang
Accrual: 0/26

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