

# Breast Disease-Oriented Team

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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: 3/10

### **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

## COGNITIVE IMPAIRMENT

### UCI 24-05

Riluzole PO vs. placebo PO  
Perceived worsening of cognitive function

PI: Chan  
Coord: Randy Kang  
Accrual: 5/26

## 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: 7/15

### NRG BR009 (OFSET)

Arm 1: Ovarian Function Suppression (OFS) + AI  
 Arm 2: Adj Chemo + OFS + AI  
 Oncotype-DX Recurrence Score  $\leq$  18 (unless T1a tumor) required  
 PI: Parajuli  
 Coord: TBD  
 Accrual: 0/10

### UCI 23-192 (WIDER)

Ribociclib 400mg + SOC ET + Goserelin or Leuprolide  
 Exploratory cohort is same treatment  
 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: 2/5

### UCI 23-162

PARP1 Selective Inhibitor, IMP1734 for any HER2-  
**Cohort 1A:** Monotherapy  
**Cohort 1C:** IMP1734 + Paclitaxel 80mg/m<sup>2</sup>  
**Part 3:** PARPi-treated vs PARPi-naïve  
 PI: Rezazadeh  
 Coord: Ali/TBD  
 Accrual: 0/5

## ER+

### A012301 (LoTam)

Low Dose Tamoxifen Vs SOC endocrine therapy for Low risk (defined in notes)  
 PI: Parajuli  
 Coord: TBD  
 Accrual: 0/15

## HER2+

## TNBC

### UCI 23-162

PARP1 Selective Inhibitor, IMP1734 for any HER2-

**Cohort 1A:** Monotherapy

**Cohort 1C:** IMP1734 + Paclitaxel 80mg/m<sup>2</sup>

**Part 3:** PARPi-treated vs PARPi-naïve

PI: Rezazadeh

Coord: Ali/TBD

Accrual: 0/5

### UCI 24-195

PF-08046054 (an ADC) monotherapy

**Dose ESC (Part A) or Schedule Optimization (Part B):**

PD-L1 expression ≥1 TPS, CPS, or % IC

**Signal-seeking cohort:**

**Biology cohort:**

PI: Nagasaka

Coord: TBD

Accrual: 0/6

## COGNITIVE IMPAIRMENT

### UCI 24-05

Riluzole PO vs. placebo PO  
Perceived worsening of cognitive function

PI: Chan  
Coord: Randy Kang  
Accrual: 5/26



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: 5/10

**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: Randy Kang

Accrual: 4/5

**UCI 23-162**

PARP1 Selective Inhibitor, IMP1734 for any HER2-

**Cohort 1A**: Monotherapy**Cohort 1C**: IMP1734 + Paclitaxel 80mg/m<sup>2</sup>**Part 3**: PARPi-treated vs PARPi-naïve

PI: Rezazadeh

Coord: Ali/TBD

Accrual: 0/5

2L+

**UCI 25-28**

DOT Approved, ATV-1601 monotherapy

No more than 1 line in this setting

Cohort A: AKT1E17K mutations

Cohort C: PIK3CA or PTEN LoF mutations

Cohort D: AKT1E17K mutations – combo w/ fulvestrant

PI: Lavasani

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  $\geq 1+$ )**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: Randy Kang

Accrual: 2/5

2L+

**UCI 25-81**

DOT Approved, Evorpaccept (ALX148)  
Locally adv or Mets HER2+ prior T-DXd relapsed in 6month  
Physician Choice then either Cohort 1 or 2

**Cohort 1:** ALX148+Trastuzumab+Chemo

**Cohort 2:** Trastuzumab+Chemo

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: 5/10

**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 23-162**

PARP1 Selective Inhibitor, IMP1734  
for any HER2-

**Cohort 1A:** Monotherapy

**Cohort 1C:** IMP1734 + Paclitaxel  
80mg/m<sup>2</sup>

**Part 3:** PARPi-treated vs PARPi-naïve

PI: Rezazadeh  
Coord: Ali/TBD  
Accrual: 0/5

**UCI 24-08**

SPEDOX-6 IV

PI: Chow  
Coord: TBD  
Accrual: 0/50

**ETCTN 10546**

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

PI: Parajuli  
Coord: Randy Kang  
Accrual: 1/5

**UCI 24-195**

PF-08046054 (an ADC) monotherapy

**Dose ESC (Part A) or Schedule**

**Optimization (Part B):**

PD-L1 expression  $\geq 1$  TPS, CPS, or % IC

**Signal-seeking cohort:**

**Biology cohort:**

PI: Nagasaka  
Coord: TBD  
Accrual: 0/6

**METASTATIC: 1L+**

UCI 25-09  
DOT approved  
BL-B01D1 (BMS-986507) vs SOC  
Not candidates for anti-PD1/PD-L1  
chemo combo  
PI: Parajuli  
Coord: TBD  
Accrual: 0/6

ALL

## 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: 4/5

## 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  
Accrual: 1/5

### 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

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: 3/10

### UCI 25-75

CRN09682 IV (an MMAE) for SST2-expressing solid tumors  
Slot Req???

Breast Coord: TBD

PI: Dr. Dayyani  
Accrual: 0/15



## NEUROPATHY

**ALLIANCE A222101**

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

PI: Parajuli  
Coord: Randy Kang  
Accrual: 0/30

## COGNITIVE IMPAIRMENT

**UCI 24-05**

Riluzole PO vs. placebo PO  
Perceived worsening of cognitive function

PI: Chan  
Coord: Randy Kang  
Accrual: 5/26

## Other/LTFU

UCI 25-58 Calibr  
DOT Approved  
Subjects about to receive at least one CLBR001 cell dose.  
Will be on LTFU for study

PI: Lavasani  
Coord: TBD  
Accrual: 0/5

UCI 25-43  
Type 1 Hybrid Effectiveness of a Patient-reported  
outcomes

PI: Chan  
Coord: TBD  
Accrual: 0/5

**BASIC SCIENCE****UCI 18-136**

PI: Parajuli  
Coord: Billy Joel Sanchez/Caylee Carlton  
Accrual: 74/100

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

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

A232403  
DOT Approved  
Financial Hardship study  
PI: Lavasani  
Coord: TBD  
Accrual: 0/5

**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

**UCI 25-25**

PI: Eakin  
Coord: TBD  
Accrual: 0/5