

Breast Disease-Oriented Team

Clinical Research Treatment Trial Flowchart
CRC Contact: GRP - CTU Breast Coordinators (CTUBreastCRC@hs.uci.edu)
Clinical Research Manager: Juan Miranda



ALL

UCI 24-05

Riluzole PO vs. Placebo PO

Perceived worsening of *cognitive function*

BREAST COHORT FULL

PI: Chan

CRC: Randy Kang

Accrual: 19/39

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
 CRC: Madeleine Phan
 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
 CRC: TBD
 Accrual: 0/10

UCI 25-48

Riluzole PO vs. Placebo PO
 Perceived worsening of cognitive function

PI: Chan
 CRC: TBD
 Accrual: 0/20



Adjuvant Therapy – HER2-

HR+

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
 CRC: Madeleine Phan
 Accrual: 0/10

ER+

A012301 (LoTam)
 Low Dose Tamoxifen Vs SOC endocrine therapy for Low risk (defined in notes)

 PI: Parajuli
 CRC: Juan Miranda
 Accrual: 11/30

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

 PI: Mehta
 CRC: Stephany Ruiz
 Accrual: 3/5

UCI 23-192 (WIDER)
 Ribociclib 400mg + SOC ET + Goserelin or Leuprolide
 Exploratory cohort is same treatment

 PI: Parajuli
 CRC: Stephany Ruiz
 Accrual: 0/5

UCI 24-116
 Arm A: Elacestrant PO (SERD)
 Arm B: Physician's choice endocrine Tx

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

HER2+

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

TNBC



2L+

UCI 19-145 (HR+/HER2-)
 CDK 4/6 inhibitor+ER Regulator+Aromatase Inhibitor

CRCs: Stephany Ruiz, Michael Rodriguez, Madeleine Phan
 Accrual: 21/40

2L+

UCI 22-09 (TNBC, HR+/HER2-)
 XMT-1660 (ADC) – BC, EC, OC, ACC-I
 Dose Esc, Backfill Cohort, Exp
SLOT RSVP REQ (HR+/TNBC COHORT TEMP CLOSED)

PI: Parajuli
 CRC: Juan Miranda
 Accrual: 7/10

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+

Metastatic: HER2 Low, HER2+

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

SLOT RSVP REQ (Dose Esc)

Dose Esc (Ph Ib):

Cohort A: Zongertinib (BI 1810631; HER2 inhibitor) + T-DM1
 Cohort B: BI 1810631 + T-DXd
 Cohort K:
 Zongertinib+Trastuzumab

PI: Dayyani
 CRC: Randy Kang
 Accrual: 3/10

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
 CRC: Randy Kang
 Accrual: 2/5

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

CRC: My Nguyen; Breast CRC TBD
 Accrual: 2/10

UCI 25-81/UCI 25-81-03 (HER2+)

Locally adv or Mets HER2+ prior T-DXd relapsed in 6month Physician Choice then either Cohort 1 or 2

Cohort 1: Evorpaccept (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 (HR+/TNBC COHORT TEMP CLOSED)

PI: Parajuli

CRC: Juan Miranda

Accrual: 6/10

ETCTN 10546

ASTX727 (Cytidine deaminase (CDA) inhibitor + nucleoside hypomethylating agent (HMA)) + Paclitaxel +

Pembrolizumab

DL-2 now open for TNBC

SLOT RSVP REQ

PI: Parajuli

CRC: Randy Kang

Accrual: 1/5

UCI 24-08

SPEDOX-6 IV

SLOT RSVP REQ

PI: Chow

CRC: Erin Torrison; Breast CRC TBD

Accrual: 3/67

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: ADC monotherapy

Biology cohort: ADC monotherapy

PI: Nagasaka

CRC: TBD

Accrual: 0/6

METASTATIC: 1L+



ALL

UCI 25-52

PC14586 drug for Locally Advanced or Metastatic Solid Tumors with TP53 Y220C mutation (PYNNALE)
SLOT RSVP REQ

CRC: Keagan Buttigieg; Breast CRC TBD

PI: Arter
Accrual: 0/5

UCI 24-197

TNG456 Monotherapy or Combined w/Abemaciclib in solid tumors with MTAP Loss
SLOT RSVP REQ

CRC: TBD

PI: Park
Accrual: 0/5

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
SLOT RSVP REQ

PI: Uchio
CRC: TBD
Accrual: 0/4



ALL

UCI 22-26

CB-03-10 (PO; AR and GR antagonist)

Part 1 (esc): adv/met solid tumor

Part 2 (exp): adv/met solid tumor or relapsed/refractory
TNBC

SLOT RSVP REQ

HPB/Panc CRC: Miranda Duron

Breast CRC: TBD

PI: Dayyani

Accrual: 11/12

UCI 25-75

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

CRC: TBD

PI: Dayyani

Accrual: 0/15



ALL

NRG CC014

SOC vs SOC + RT for High-risk Asymptomatic Bone Metastases

SLOT RSVP REQ

PI: Harris

CRC: Natalie Arechiga; Breast CRC TBD

Accrual: 1/10

Other/LTFU

UCI 25-43

Type 1 Hybrid Effectiveness of a Patient-Reported Outcomes

PI: Chan

CRC: TBD

Accrual: 0/5



BASIC SCIENCE

SUPPORTIVE CARE

UCI 18-136
6 slots for Cohort 1/neo-adjuvant and 13 slots for Cohort 2/adjuvant
PI: Parajuli
CRC: Caylee Carlton
Accrual: 77/100

UCI 24-64
High fiber diet as therapy response and reduce recurrence

PI: Whiteson
CRC: TBD
Accrual: 0/60

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

PI: Parajuli
CRC: Billy Joel Sanchez
Accrual: 49/75

UCI 25-83
Mobile Health Intervention to Improve Adherence to Oral Anticancer Therapy
PI: Sadigh
CRC: TBD
Accrual: 8/30

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

UCI 25-115
Couples Intervention for Young Adult Cancer Survivors: A Pilot Study
PI: Hoyt
CRC: TBD
Accrual: 0/5



HEALTH SERVICES RESEARCH

UCI 25-25

PI: Eakin
CRC: TBD
Accrual: 0/150

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended