

Breast Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

ALL

UCI 24-05

Riluzole PO vs. placebo PO
Perceived worsening of *cognitive function*

PI: Chan
Coord: Randy Kang
Accrual: 15/39

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

Coord: 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

Coord: TBD

Accrual: 0/10

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: Juan Miranda
 Accrual: 0/10

ER+

A012301 (LoTam)

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

PI: Parajuli
 Coord: Randy Kang
 Accrual: 2/15

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 23-192 (WIDER)

Ribociclib 400mg + SOC ET + Goserelin or Leuprolide
 Exploratory cohort is same treatment

PI: Parajuli
 Coord: TBD
 Accrual: 0/5

UCI 24-116

Arm A: Elacestrant PO (SERD)
 Arm B: Physician's choice endocrine Tx

PI: Parajuli
 Coord: TBD
 Accrual: 0/5

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

HER2+

TNBC

2L+

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

XMT-1660 (ADC) – BC, EC, OC, ACC-I

Dose Esc, Backfill Cohort, Exp

SLOT RSVP REQ (HR+ COHORT TEMP CLOSED)

PI: Parajuli

Coord: Juan Miranda

Accrual: 6/10

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 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)**

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

Coord: Randy Kang

Accrual: 3/10

UCI 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

UCI 25-81 (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

PI: Parajuli

Coord: Juan Miranda

Accrual: 6/10

UCI 24-08

SPEDOX-6 IV

SLOT RSVP REQ

PI: Chow

Coord: TBD

Accrual: 3/67

ETCTN 10546ASTX727 (Cytidine deaminase (CDA)
inhibitor + nucleoside

hypomethylating agent (HMA)) +

Paclitaxel + Pembrolizumab

*DL-2 now open for TNBC***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 ≥ 1 TPS, CPS, or % IC**Signal-seeking cohort:** ADC

monotherapy

Biology cohort: ADC monotherapy

PI: Nagasaka

Coord: TBD

Accrual: 0/6

METASTATIC: 1L+

UCI 25-09

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

ALL

UCI 25-52

PC14586 drug for Locally Advanced or Metastatic Solid Tumors with TP53 Y220C mutation (PYNNAACLE)
Slot Req

Breast Coord: TBD

PI: Dr. Arter
Accrual: 0/5

UCI 24-197

TNG456 Monotherapy or Combined w/Abemaciclib in solid tumors with MTAP Loss
Slot Req

Breast Coord: TBD

PI: Dr. 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

PI: Uchio
CRC: Phil Duffy/TBD
Accrual: 0/4

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: 11/12

UCI 25-75

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

Breast Coord: TBD

PI: Dr. Dayyani
 Accrual: 0/15

ALL

NRG CC014

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

SLOT RSVP REQ???

PI: Harris
Coord: Natalie Arechiga
Accrual: 1/10

Other/LTFU

UCI 25-43

Type 1 Hybrid Effectiveness of a Patient-reported
outcomes

PI: Chan
Coord: TBD
Accrual: 0/5

BASIC SCIENCE

UCI 18-136

6 slots for Cohort 1/neo-adjuvant and 13 slots for Cohort 2/adjuvant

PI: Parajuli

Coord: Billy Joel Sanchez/Caylee Carlton

Accrual: 76/100

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

PI: Parajuli

Coord: Billy Joel Sanchez

Accrual: 49/75

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

UCI 25-83

Mobile Health Intervention to Improve Adherence to Oral Anticancer Therapy

PI: Sadigh

Coord: TBD

Accrual: 0/60

UCI 25-115

Couples Intervention for Young Adult Cancer Survivors: A Pilot Study

PI: Hoyt

Coord: TBD

Accrual: 0/5

HEALTH SERVICES RESEARCH**UCI 24-28**

PI: Sadigh
Coord: TBD
Accrual: 29/90

UCI 25-25

PI: Eakin
Coord: TBD
Accrual: 0/5