

# Genitourinary Disease-Oriented Team

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Clinical Research Treatment Trial Flowchart

OBSERVATIONAL

SUPPORTIVE CARE

UCI 20-59 (UCI)

6 Sessions of Goal-focused Emotion-Regulation Therapy (GET) or Individual Supportive Psychotherapy (ISP)

PI: Hoyt

Coord: M. Haydon

Accrual 26/200

NON-TREATMENT

UCI 98-41 (UCI)

PI: Ahlering  
 Coord: J. Tran  
 Accrual 2539/3380

UCI 17-07 (UCI)

PI: Ahlering  
 Coord: J. Tran  
 Accrual 894/1875

UCI 00-55 (UCI)

PI: Ahlering  
 Coord: L. Huynh  
 Accrual 429/450

UCI 17-40 (UCI)

PI: Uchio  
 Coord: P. Duffy  
 Accrual 972/1027

UCI 23-223 (Curium)

Ph3 Cu64 PSMA I&T PETCT for newly dx prostate patients

PI: Uchio  
 Coord: TBD  
 Accrual 1/10

UCI 23-159

PI: Cozen  
 Coord: TBD  
 Accrual 0/240

UCI 23-137

PI: Lee  
 Coord: A. Raad  
 Accrual 7/400

NON-TREATMENT

UCI 24-60 (UCI)

Qualitative semi-structured interviews

PI: Hoyt  
Coord: TBD  
Accrual 7/20

UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Seyedin  
Coord: TBD  
Accrual 0/50

UCI 24-128 (UCI)

Questionnaires, counseling, saliva collection

PI: Hoyt  
Coord: TBD  
Accrual 0/100

## RT

NRG GU009

De-intensification (Decipher < 0.85): RT + 12/24 mo ADT  
 Intensification (Decipher > 0.85 or Node +): RT + 24mo ADT +/- 24 mo - CLOSED  
 Apalutamide (ARI) – CLOSED ON 9/10/24

PI: Hong  
 Coord: J. Loaiza  
 Accrual 8/10

NRG GU010

De-intensification (Decipher < 0.40): RT + 6 mo ADT  
 Intensification (Decipher 0.40-0.60 vs >0.60): RT + 6mo ADT +/- 6 mo  
 darolutamide

PI: Hong  
 Coord: J. Loaiza  
 Accrual 0/10

NRG GU011

SABR + blinded placebo or Relugolix (ADT) for 6mo

PI: Hong  
 Coord: A. Macaraeg  
 Accrual 1/3

NRG GU013

Arm 1: SBRT (ultrahypofractionation) 5 fractions  
 Arm 2: Conventional or moderate hypofractionation 20-45 fractions

PI: Hong  
 Coord: J. Loaiza  
 Accrual 1/10

## HORMONE THERAPY

## MULTIPLE LINES OF THERAPY

### ETCTN 10301

Ph1 completed, Ph2 open to accrual

- A: 223Ra (bone-targeted alpha particle emitting radiopharmaceutical) IV x6
- B: 223Ra IV x6 + M3814 (DNA-PK inhibitor) PO BID
- C: 223Ra IV x6 + avelumab (anti-PD-L1 IgG1 Ab) IV x10 + M3814 PO BID

PI: Mar  
Coord: A. Macaraeg  
Accrual 12/17

### UCI 23-118 (Merck)

- Arm 1: MK-5684 + HRT (appx. 600)
- Arm 2: Alternative Abiraterone or Enzalutamide (appx. 600)

PI: Rezazadeh  
Coord: J. Wang  
Accrual 0/6

### UCI 23-119 (Merck)

- Arm 1: MK-5684 + HRT (appx. 600)
- Arm 2: Alternative Abiraterone or Enzalutamide (appx. 600)

PI: Rezazadeh  
Coord: J. Wang  
Accrual 3/9

### UCI 23-204 (TELIX)

- Cohort 1: TLX591 + abiraterone
- Cohort 2: TLX591 + enzalutamide
- Cohort 3: TLX591 + docetaxel

PI: Srinivas  
Coord: J. Loaiza  
Accrual 0/20

MUTATION-SPECIFIC

ETCTN 10603

M1774 (ATR) first 14 days of each cycle  
REQ SLOT RSVP

PI: Rezazadeh  
Coord: J. Wang  
Accrual 0/5

UCI 22-78 (Roche)

Arm 1: MK-5684 + HRT (appx. 600)  
Arm 2: Alternative Abiraterone or Enzalutamide  
(appx. 600)

PI: Tewari  
Coord: J. Ejbara  
Accrual 0/3

UCI 23-162 (Eikon)

Dose escalation open: IMP1734 oral

PI: Rezazadeh  
Coord: A. Raad  
Accrual 0/5



NON-TREATMENT

ADJUVANT

UCI 13-03 (UCI)

Office-Based Percutaneous Ultrasound-Guided Renal Biopsy

PI: Landman  
Coord: R. Yoon  
Accrual: 14/225

1L

UCI 22-130 (VUMC)

Ipi (anti-CTLA-4)/Nivo (anti-PD1) VS Nivo/Cabo (anti-VEGF TKI)

PI: Mar  
Coord: A. Castro  
Accrual 5/9

MULTIPLE LINES OF THERAPY

ETCTN 10144

Olaparib (PARP inhibitor) PO

Non-prostate GU tumors with DNA-repair defects (BRCA1, BRCA2, ATM, BAP1, MSH2, PALB2, and BRIP1 and others)

PI: Rezazadeh  
Coord: A. Castro  
Accrual 2/6

UCI 22-171 (Dragonfly Therapeutics)

DF9001 (TriNKET™) +/- Nivo (anti-PD1)

EGFR exp/amp via FISH or NGS

PI: Valerin  
Coord: M. Nguyen  
Accrual: 4/25

NON-INVASIVE

Ta, T1, CIS

Low Grade

UCI 18-53 (Merck)

PI: Uchio  
 Coord: D. Hassan  
 Accrual 23/30

UCI 21-37 (Steba)

PI: Uchio  
 Coord: TBD  
 Accrual: 2/5

UCI 23-202 (Janssen)

TAR-200 vs. investigator's choice of chemotherapy

PI: Uchio  
 Coord: TBD  
 Accrual: 1/3

Unspecified

UCI 21-41 (Astellas)

PI: Uchio  
 Coord: D. Hassan  
 Accrual 1/2

UCI 22-69 (enGene)

PI: Uchio  
 Coord: P. Duffy  
 Accrual 0/5

MUSCLE INVASIVE

UCI 21-09  
(AstraZeneca)

Arm 1: Neoadjuvant Durva + Treme + EV → RC → adjuvant Durva + Treme → Durva  
 Arm 2: Neoadjuvant Durva + EV → RC → adjuvant Durva  
 Arm 3: RC → observation/approved adjuvant SOC

PI: Rezazadeh  
 Coord: A. Castro  
 Accrual 6/8

UCI 23-72

Outcomes with use of multi parametric MRI (mpMRI) compared to diagnostic Transurethral Resection of Bladder Tumor (TURBT) in patients with suspected MIBC

PI: Mar  
 Coord: A. Macaraeg  
 Accrual 13/30

ALL-COMERS

### GOG 3082 (Acrivon)

Arm 1: OncoSignature (+): ACR-368 IV  
 Arm 2: OncoSignature (-): ULDG IV + ACR-368 IV

PI: Mar  
 Coord: A. Castro  
 Accrual 4/10

### UCI 22-128 (Merck)

MK-2140 (Zilovertamab Vedotin) IV D1/D8 Q3W

PI: Rezazadeh  
 Coord: J. Loaiza  
 Accrual 0/3

### UCI 22-129 (Merck)

Part 1 (safety lead-in)  
 Arm A: EV IV + MK-4280A IV  
 Arm B: EV IV + MK-7684A IV  
 Arm C: EV IV + Pembro IV  
Part 2 (expansion)  
 Arm A and/or B  
 Arm C: EV IV + Pembro IV

PI: Rezazadeh  
 Coord: J. Loaiza  
 Accrual 0/6

### SWOG S1937

Arm 1: SOC (physician's choice)  
 Arm 2: Eribulin – PERMANENTLY CLOSED  
 Arm 3: Eribulin + Gemcitabine

PI: Mar  
 Coord: A. Raad  
 Accrual 3/5

**MUTATION-SPECIFIC**

**ETCTN 10144**

Olaparib (PARP inhibitor) PO

Non-prostate GU tumors with DNA-repair defects (BRCA1, BRCA2, ATM, BAP1, MSH2, PALB2, and BRIP1 and others)

PI: Rezazadeh  
 Coord: A. Castro  
 Accrual 2/6

**UCI 22-39 (SeaGen)**

Cohort A: DV (HER2-positive) IHC 3+, or IHC 2+ and ISH-positive

Cohort B: DV (HER2-low) IHC 2+ and ISH-negative, or IHC 1+

Cohort C: Randomized arm open

Pi: Mar  
 Coord: A. Castro  
 Accrual 5/5

## PREVENTATIVE

## HEALTH SERVICES RESEARCH

### UCI 21-174 (UCI)

Preserving Medical Records After a Cancer Diagnosis for Subsequent Generations to Use

PI: Zell

Coord: TBD

Accrual: 0/100

## SUPPORTIVE CARE

## DIAGNOSTIC

### UCI 23-127 (UCI)

Stress & Coping in Asian Americans with Advanced/Metastatic Cancer

PI: Jacqueline Hyo Ju Kim

Coord: TBD

Accrual: 54/400

## MUTATION-SPECIFIC

UCI 19-64 (Merus N.V.)

MCLA-128 (IgG1 bispecific Ab)

Documented NRG1 fusion

Group H: Non pancreatic/NSCLC solid tumors

PI: Nagasaka

Coord: C. Ramirez

Accrual 8/10

UCI 23-66 (Boehringer  
Ingelheim)

BI 1810631 (EGFR wt sparing, selective HER2 inhibitor) PO

ER2 aberration (over-ex/gene amp/non-synonymous somatic mut/gene rearrangement involving HER2 or NRG1) positive tumors

PI: Nagasaka

CRC: C. Smith

Accrual: 2/5

UCI 21-13 (Bicycle Tx  
Ltd)

EphA2 Expression

Part A: Malignant solid tumors

Part B monotherapy: Met UC

PI: Nagasaka

Coord: R. Chang

Accrual: 2/3

UCI 22-87 (Revolution  
Med)

\*1L

Documented KRAS G12A, G12D, G12R, G12S, G12V

SLOT RSVP REQ

PI: Ou

Coord: J. Choe

Accrual: 19/25

UCI 23-116 (Revolution  
Med)

1b Dose Escalation + Expansion: RMC-6291 &amp; RMC-6236

Documented KRAS-G12C

SLOT RSVP REQ

PI: Ou

Coord: K. Buttigieg

Accrual: 0/10

UCI 24-82 (Ikema)

Ph1 first in-human of IK-595 (oral dual MEK/RAF inhibitor)

PI: Valerin

Coord: N. Ferrand

Accrual: 0/10



## ALL-COMERS

## UCI 20-67 (Dragonfly Therapeutics)

Anti-PD-1 DF1001 (monotherapy or combination therapy)

LA/mUC TCC of urothelium (renal pelvis, ureters, urinary urothelial, urethra).

PI: Valerin  
Coord: M. Nguyen  
Accrual: 18/20

## UCI 21-146 (Shanghai Miracogen)

Anti-Tissue Factor monoclonal antibody-BCNvcMMAE conjugate

Cohort A panc cancer open only as of 3/18/24

PI: Dayyani  
Coord: C. Kang  
Accrual: 5/11

## UCI 21-40 (Dragonfly Therapeutics)

DF6002 +/- Nivo  
**SLOT RSVP REQ**

LA/m UC, renal, prostate

PI: Valerin  
CRC: B. Huynh  
Accrual: 5/6

## UCI 22-26 (Cosmo Technologies)

Androgen and glucocorticoid receptor antagonist

Part 1 (dose esc): Relapsed/refractory adv/met solid tumor

Part 2 (dose exp): Relapsed/refractory adv/met solid tumors TBD (likely prostate adeno)

PI: Dayyani  
Coord: N. Ferrand  
Accrual: 8/12

## ALL-COMERS

UCI 23-186

Currently on Treatment or in Follow-up in Studies That Include Pembrolizumab

PI: Tewari  
Coord: J. Ejbara  
Accrual 0/10

UCI 23-200

Participants with Advanced Solid Tumors Expressing Claudin

PI: Dayyani  
Coord: S. Duong/J. Koff  
Accrual 2/10

UCI 23-07 (Poseida Therapeutics, Inc.)

Cyclophosphamide (300 mg/m<sup>2</sup>) and fludarabine (30 mg/m<sup>2</sup>) IV

Part 1 (dose esc) and Part 2 (dose exp)

PI: Mehta  
Coord: J. Miranda  
Accrual: 0/5

ETCTN-10558

Triapine + 177Lu-dotatate vs. 177Lu dotatate alone for well-differentiated somatostatin receptor-pos NETs

PI: Dayyani  
Coord: H. Nguyen  
Accrual: 0/3

ALL-COMERS

UCI 24-28

Surveys for all newly diagnosed cancer pts

PI: Sadeghi

Coord: R. Kao

Accrual: 29/90