

# Genitourinary Disease-Oriented Team

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Clinical Research Treatment Trial Flowchart



OBSERVATIONAL

SWOG S1823

Low risk group (Stage I/IA)  
Moderate risk group (Stage IIA/IB)  
High risk group (nonseminoma Stage IS only)

PI: Rezazadeh  
Coord: K. Cung  
Accrual 4/8

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 7/200



■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

NON-TREATMENT

UCI 98-41 (UCI)

PI: Ahlering  
Coord: J. Tran  
Accrual 2453/3380

UCI 17-07 (UCI)

PI: Ahlering  
Coord: J. Tran  
Accrual 833/1875

UCI 23-222 (Curium)

Ph3 Cu64 PSMA I&T PETCT for pts with biochemical recurrence  
PI: Uchio  
Coord: TBD  
Accrual 0/10

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 0/10

UCI 23-159

PI: Cozen  
Coord: TBD  
Accrual 0/240

UCI 23-137

PI: Lee  
Coord: TBD  
Accrual 0/400



**NON-TREATMENT**

**UCI 24-60 (UCI)**

Qualitative semi-structured interviews

PI: Hoyt  
Coord: TBD  
Accrual 0/20

## RT

NRG GU009

De-intensification (Decipher < 0.85): RT + 12/24 mo ADT  
 Intensification (Decipher > 0.85 or Node +): RT + 24mo ADT +/- 24 mo  
 Apalutamide (ARi)

PI: Hong  
 Coord: J. Loaiza  
 Accrual 5/10

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

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

## 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 8/12

### 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 0/5

### 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 0/5



## 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 0/5

### 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

MULTIPLE LINES OF THERAPY

UCI 22-53 (Roche)

Control: Pembro (anti-PD1) IV + Axitinib (TKI) PO  
 A: Tobemstomig (IgG1 BsAb) IV + Axitinib PO  
 B: Tiragolumab (IgG1k mAb) IV + Tobemstomig IV + Axitinib PO

PI: Mar  
 Coord: A. Raad  
 Accrual 5/10

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: 3/15

UCI 22-130 (VUMC)

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

PI: Mar  
 Coord: A. Castro  
 Accrual 0/9



**NON-INVASIVE**

**Urothelial – Localized/Regional**

Ta, T1, CIS

Low Grade

**UCI 18-53 (Merck)**

PI: Uchio  
 Coord: D. Hassan  
 Accrual 21/30

**UCI 21-37 (Steba)**

PI: Uchio  
 Coord: TBD  
 Accrual: 1/5

**UCI 23-202 (Janssen)**

TAR-200 vs. investigator's choice of chemotherapy

PI: Uchio  
 Coord: TBD  
 Accrual: 0/3

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 3/8

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 5/30



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 3/10

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 0/5



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 4/5



**PREVENTATIVE**

**UCI 22-109 (Xiamen LP  
Pharmaceutical)**

Palonosetron IV vs. Buccal film anti-emetic

PI: Dayyani  
Coord: P. Yang  
Accrual: 1/30

**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**

**UCI 21-127 (UCI)**

Goal Directed Intervention for Adolescent and  
Young Adult Cancer Survivors

Age 15-21

PI: Michelle Fortier  
Coord: TBD  
Accrual: 0/100

**DIAGNOSTIC**

**UCI 23-127 (UCI)**

Stress & Coping in Asian Americans with  
Advanced/Metastatic Cancer

PI: Jacqueline Hyo Ju Kim  
Coord: TBD  
Accrual: 13/60



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: 0/5

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: O. Quines  
Accrual: 14/20

UCI 23-116 (Revolution Med)

1b Dose Escalation + Expansion: RMC-6291 & RMC-6236  
Documented KRAS-G12C  
**SLOT RSVP REQ**  
  
PI: Ou  
Coord: K. Buttigieg  
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 21-208 (IGM Biosciences, Inc.)

IGM-8444 evaluated for 2 different dosing frequencies

PI: Chow  
Coord: M. Nguyen  
Accrual: 9/15

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: 7/12





ALL-COMERS

UCI 22-37 (Tachyon Therapeutics)

Ph 1a only: any solid tumor

PI: Dayyani  
Coord: A. Luna  
Accrual: 5/10

UCI 22-42

Part 1: TransCon TLR7/8 Agonist IT injection  
Part 2: TransCon TLR7/8 Agonist IT injection + Pembro IV

Part 1: Any solid tumor  
Part 2: Indications where monotherapy pembro has known/exp clinical activity

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

UCI 23-07 (Poseida Therapeutics, Inc.)

Cyclophosphamide (300 mg/m2) and fludarabine (30 mg/m2) IV

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

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

UCI 23-186

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

PI: Tewari  
Coord: TBD  
Accrual 0/5

UCI 23-200

Participants with Advanced Solid Tumors Expressing Claudin

PI: Dayyani  
Coord: TBD  
Accrual 0/10



ALL-COMERS

UCI 24-28

Surveys for all newly diagnosed cancer pts

PI: Sadeghi  
Coord: TBD  
Accrual: 0/90