

Genitourinary Disease-Oriented Team

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 2565/3380

UCI 17-07 (UCI)

PI: Ahlering
Coord: J. Tran
Accrual 920/1875

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 16/400



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



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

HORMONE THERAPY

Prostate – Hormone



■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

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

UCI 24-79 (Amgen)

PI: Rezazadeh
 Coord: TBD
 Accrual 0/10

SWOG S1802

- Arm 1: SST Only
- Arm 2: SST and Definitive Treatment of Primary Tumor

PI: Gin
 Coord: Jamie Wang
 Accrual 0/15



MUTATION-SPECIFIC

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

MULTIPLE LINES OF THERAPY

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

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 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 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 7/8

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 14/30

UCI 23-59

- 1.Radical cystectomy or nephroureterectomy
- 2.High-risk UC based onsurgical pathology
- 3.Sacituzumab Govitecan PLUS Nivolumab

PI: Mar
Coord: J. Loaiza
Accrual 0/32



ALL-COMERS

UCI 22-128 (Merck)

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

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

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

UCI 24-46(Ferring)

PI: Uchio
Coord: TBD
Accrual 0/6



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 6/5



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: 55/400



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 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 & RMC-6236
Documented KRAS-G12C
SLOT RSVP REQ

PI: Ou
Coord: K. Buttigieg
Accrual: 0/10

UCI 24-82 (Ikena)

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 3/10

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

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: 41/90