

Genitourinary Disease-Oriented Team

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 3/8

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 6/200

NON-TREATMENT

UCI 98-41 (UCI)

PI: Ahlering
Coord: J. Tran
Accrual 2378/3380

UCI 17-07 (UCI)

PI: Ahlering
Coord: J. Tran
Accrual 719/1875

UCI 19-25 (UCI)

PI: Bristow
Coord: TBD
Accrual 0/36400

UCI 00-55 (UCI)

PI: Ahlering
Coord: E. Huang
Accrual 429/450

UCI 17-40 (UCI)

PI: Uchio
Coord: TBD
Accrual 972/600

UCI 19-48 (Johns Hopkins)

PI: Ahlering
Coord: TBD
Accrual 0/12

UCI 23-159

PI: Cozen
Coord: TBD
Accrual 0/240

RT

HORMONE THERAPY

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: Seyedin
Coord: J. Loaiza
Accrual 3/10

NRG GU011

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

PI: Seyedin
Coord: A. Macaraeg
Accrual 1/5

NRG GU013

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

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

MULTIPLE LINES OF THERAPY

ETCTN 10301

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 7/12

ALLIANCE A032101

Interrupt ADT + ARPI with re-initiation triggers

PI: Rezazadeh
 Coord: J. Loaiza
 Accrual 6/10

UCI 23-119 (MERCK)

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

PI: Rezazadeh
 Coord: TBD
 Accrual 0/5

UCI 23-118 (MERCK)

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

PI: Rezazadeh
 Coord: TBD
 Accrual 0/5

MUTATION-SPECIFIC

ETCTN 10603

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

PI: Rezazadeh
Coord: J. Wang
Accrual 3/5

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 0/10

NON-TREATMENT

UCI 13-03 (UCI)

Office-Based Percutaneous Ultrasound-Guided Renal Biopsy

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

ADJUVANT

UCI 21-228 (Merck)

9 Cycles of adjuvant Pembro anti-PD1) + Belzutifan (HIF-2 α /placebo
(double blinded)

REQ SLOT RSVP

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

1L

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 4/10

UCI 22-130 (VUMC)

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

PI: Mar
 Coord: A. Castro
 Accrual 0/5

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: 3/15

UCI 23-91 (Incyte Corporation)

INCB099280 (Oral CPI) + Ipilimumab

Part 1 (dose esc) and Part 2 (dose exp):
 Intermediate- or poor-risk advanced ccRCC

PI: Valerin
 Coord: C. Kang
 Accrual: 0/15

NON-INVASIVE

Ta, T1, CIS

UCI 18-53 (Merck)

PI: Uchio
Coord: D. Hassan
Accrual 21/15

Low Grade

UCI 21-37 (Steba)

PI: Uchio
Coord: TBD
Accrual: 1/5

UCI 21-41 (Astellas)

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

Unspecified

UCI 22-69 (enGene)

PI: Uchio
Coord: TBD
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 1/8

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: TBD
Accrual 0/30

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 2/10

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

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 3/5

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: 0/5

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 6/7

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: K. Buttigieg
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: 12/20

ETCTN-10551Dose Escalation

BRCA1/2-mutant Tumors - Metastatic Castrate-Resistant Prostate Cancer (CPRC)

PI: Parajuli
Coord: A. Chavez
Accrual: 0/5

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: 4/11

UCI 21-40 (Dragonfly Therapeutics)

DF6002 +/- Nivo
SLOT RSVP REQ

LA/m UC, renal, prostate

PI: Valerin
CRC: B. Huynh
Accrual: 4/6

UCI 21-208 (IGM Biosciences, Inc.)

IGM-8444 evaluated for 2 different dosing frequencies

PI: Chow
Coord: M. Nguyen
Accrual: 5/8

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: 6/12

ALL-COMERS

UCI 22-37 (Tachyon Therapeutics)

Ph 1a only: any solid tumor

PI: Dayyani
Coord: A. Luna
Accrual: 3/10

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: Nirali Patel
Accrual: 0/5

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: TBD
Accrual: 0/5