

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: TBD

Accrual 0/200

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

NON-TREATMENT

UCI 23-159

PI: Cozen
Coord: TBD
Accrual 0/240

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: Seyedin

Coord: A. Macaraeg

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

HORMONE THERAPY

MULTIPLE LINES OF THERAPY

MUTATION-SPECIFIC

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: S. Boggs
 Accrual 7/12

ALLIANCE A032101

Interrupt ADT + ARPI with re-initiation triggers

PI: Rezazadeh
 Coord: J. Loaiza
 Accrual 4/5

ETCTN 10603

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

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

UCI 20-138 (Arvinas)

Part A: ARV-110 (PROTAC molecule) QD or BID

PI: Rezazadeh
 Coord: J. Loaiza
 Accrual 7/10

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

MULTIPLE LINES OF THERAPY

MUTATION-SPECIFIC

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

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

MULTIPLE LINES OF THERAPY

UCI 22-53 (Roche)Control: Pembro (anti-PD1) IV + Axitinib (TKI) POA: Tobemstomig (IgG1 BsAb) IV + Axitinib POB: Tiragolumab (IgG1k mAb) IV + Tobemstomig IV + Axitinib PO

PI: Mar

Coord: A. Raad

Accrual 3/3

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 0/5

UCI 20-179 (Navire)BBP-398 (SHP2 inhibitor) PO QDREQ SLOT RSVPCohorts open: NF1 LOF, BRAF class II/III, advanced/metastatic chordoma

PI: Rezazadeh

Coord: A. Macaraeg

Accrual 1/10

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: TBD

Accrual: 0/15

NON-INVASIVE

MUSCLE INVASIVE

Ta, T1, CIS

Low Grade

UCI 18-53 (Merck)

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

UCI 21-37 (Steba)

PI: Uchio
 Coord: TBD
 Accrual: 1/5

SWOG S1806

Group 1: 7W RT + chemo
Group 2: 7W RT + chemo + atezolizumab x6 months

PI: Yaacoub
 Coord: J. Wang
 Accrual 6/10

Unspecified

UCI 21-41 (Astellas)

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

UCI 22-69 (enGene)

PI: Uchio
 Coord: TBD
 Accrual 0/5

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: S. Boggs
 Accrual 1/8

NON-INVASIVE

MUSCLE INVASIVE

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 (Zilovetamab Vedotin) IV D1/D8 Q3W

PI: Rezazadeh
 Coord: S. Boggs
 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: S. Boggs
 Accrual 2/5

UCI 20-179 (Navire)

BBP-398 (SHP2 inhibitor) PO QD
REQ SLOT RSVF

Cohorts open: NF1 LOF, BRAF class II/III, advanced/metastatic chordoma

PI: Rezazadeh
 Coord: A. Macaraeg
 Accrual 1/10

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 fusionGroup H: Non pancreatic/NSCLC solid tumors

PI: Nagasaka

Coord: C. Gonzalez

Accrual 6/7

UCI 21-161 (Bioatla)Ph 1: LA/met solid tumorsROR+ disease by BioAtla ROR2 IHC assay

PI: Nagasaka

Coord: C. Ramirez

Accrual: 0/5

**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 ExpressionPart A: Malignant solid tumorsPart B monotherapy: Met UC

PI: Nagasaka

Coord: R. Chang

Accrual: 2/3

**UCI 22-87 (Revolution
Med)***1LDocumented KRASG12 A, G12D, G12R, G12S, G12VSLOT RSVP REQ

PI: Ou

Coord: O. Quines

Accrual: 7/20

ETCTN-10551Dose EscalationBRCA1/2-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

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: B. Huynh
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 23-101 (BMS)

Part 1A (dose esc): BMS-986288 (anti-CTLA-4 NF
Proboddy mAb) IV

Part 1A only: adv/met/unresectable RCC, UC

PI: Dayyani
CRC: TBD
Accrual: 0/10

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: TBD
Accrual: 0/5

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