

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 51/175

NON-TREATMENT

UCI 98-41 (UCI)

PI: Ahlering
Coord: J. Tran
Accrual 2647/3380

UCI 17-07 (UCI)

PI: Ahlering
Coord: J. Tran
Accrual 1000/1875

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 3/10

UCI 23-159

PI: Cozen
Coord: TBD
Accrual 0/240

UCI 23-137

PI: Lee
Coord: J. Go
Accrual 37/400

UCI 24-60 (UCI)

Qualitative semi-structured interviews

PI: Hoyt
Coord: TBD
Accrual 10/20

UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Seyedin
Coord: TBD
Accrual 0/50



NON-TREATMENT

UCI 24-128 (UCI)

Questionnaires, counseling, saliva collection

PI: Hoyt
Coord: TBD
Accrual 4/100

UCI 24-185 (HistoSonics)

GE LOGIQ E10s US, CT, and MRI

PI: Uchio
Coord: P. Duffy
Accrual 4/10

UCI 25-54 (UCI)

64Cu-SAR-bisPSMA Positron Emission Tomography

PI: Uchio
Coord: H. Dimisuyay
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 - CLOSED
Apalutamide (ARI) – CLOSED ON 9/10/24

PI: Hong
Coord: J. Loaiza
Accrual 9/10

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 1/10

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 14/17

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 4/9

UCI 23-204 (TELIX)

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

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

UCI 24-79 (Amgen)

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

SWOG S1802

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

PI: Gin
Coord: J. Wang
Accrual 1/10



MULTIPLE LINES OF THERAPY

UCI 25-84

A Phase 3, Randomized Study of Xaluritamig Monotherapy, Xaluritamig Plus Abiraterone versus Investigator's Choice

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

UCI 24-34

First-in-human, Phase 1 Dose Escalation and Expansion Study evaluating the Safety, Tolerability and Anti-tumor Activity of [225Ac] Ac-FL-020, an anti-PSMA Radioconjugate (RDC), (ProTACT)

PI: Srinivas
Coord: TBD
Accrual: 0/10



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 1/3

UCI 23-162 (Eikon)

Dose escalation open: IMP1734 oral

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

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

Alliance A032102

Arm A: Valemetostat Tosylate(3201b) (28-day cycle) Rb loss (DNA); Rb functional loss signature (RNA), NEPC signature
Arm B: Cabazitaxel + Carboplatin(21-day cycle) 2/3 TSG, FANC, HRD (DNA) ; SLFN11 signature (RNA)
Arm C: Physician choice: Cabazitaxel (21-day cycle) or AR Targeting Agent (28-day cycle) or Lutetium Lu 177 vipivotide tetraxetan (42-day cycle)
PI: Rezazadeh
Coord: J. Go
Accrual 0/5

ETCTN 10636

Phase I Trial of CA-4948 in Combination With Pembrolizumab to Overcome Resistance to PD-1/PD-L1 Blockade in Metastatic Urothelial Cancer

PI: Mar
Coord: TBD
Accrual: 1/5



MUTATION-SPECIFIC

UCI 25-55 (UCI)

Randomized, Double-blind, Placebo-controlled, Ph III
Study of Adjuvant Saruparib (AZD5305) in Patients
with BRCAm Localized High-Risk Prostate Cancer
Receiving RT with ADT

PI: Uchio
Coord: H. Dimisuay
Accrual 0/8



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 6/9

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

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 3/6

UCI 23-221

Fludarabine and Cyclophosphamide (conditioning chemotherapy) + CAR-t cell therapy

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

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 24-47 (Ferring)

Nadofaragene Firadenovec vs. observation
in IR NMIBC

PI: Uchio
Coord: TBD
Accrual 0/5

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: 2/3

Unspecified

High-Risk

UCI 22-69 (enGene)

PI: Uchio
Coord: P. Duffy
Accrual 1/5

UCI 24-139 (CG Oncology)

Cretostimogene Grenadenorepvec in HR
NMIBC
PI: Uchio
Coord: TBD
Accrual 0/10

UCI 25-86

A Study of Intravesical Bacillus Calmette-
Guerin (BCG) in Combination With ALT-803
(N-803) in Patients With Non-Muscle Invasive
Bladder Cancer

PI: Yaacoub
Coord: TBD
Accrual: 0/5

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: A. Macaraeg
Accrual 19/30

UCI 23-59

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

PI: Mar
Coord: J. Wang
Accrual 3/23

ALL-COMERS

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
 Coord: TBD
 Accrual: 0/4

UCI 22-128 (Merck)

MK-2140 (Zilovetamab 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 0/5

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 3/6

UCI 22-39 (SeaGen)

CLOSED Cohort A: DV (HER2-positive) IHC 3+, or IHC 2+ and ISH-positive
CLOSED Cohort B: DV (HER2-low) IHC 2+ and ISH-negative, or IHC 1+
OPEN Cohort C: Randomized arm open

Pi: Mar
Coord: A. Castro
Accrual 6/10



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: Kim
Coord: TBD
Accrual: 71/400



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: Nagasaka

Coord: J. Choe

Accrual: 21/25

UCI 23-116 (Revolution
Med)

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

Documented KRAS-G12C

SLOT RSVP REQ

PI: Arter

Coord: R. Chang

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: 8/10



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: 18/29

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: 5/10

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

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: 11/12

NRG CC-014

SOC vs SOC + RT for High-risk Asymptomatic Bone Metastases

PI: Harris
Coord: B. Huynh
Accrual: 0-40



ALL-COMERS

UCI 23-186

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

PI: Tewari
Coord: J. Ejbara
Accrual 1/10

UCI 23-200

Participants with Advanced Solid Tumors Expressing Claudin

PI: Dayyani
Coord: S. Duong/J. Koff
Accrual 4/10

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: 83/90

UCI 25-14

Antineoplastic Therapy

PI: Rezazadeh
Coord: TBD
Accrual: 0/50

UCI 25-83

Mobile Health Intervention to Improve
Adherence to Oral Anticancer Therapy

PI: Sadigh
Coord: TBD
Accrual: 0/60