

Genitourinary Disease-Oriented Team

Clinical Research Treatment Trial Flowchart



OBSERVATIONAL

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

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 72/175

UCI 25-167 (UCI)

Understanding Adverse Biopsychosocial Outcomes and Unmet Needs Among Long-Term Young Adult Survivors of Testicular Cancer

PI: Hoyt

Coord: M. Haydon

Accrual 0/125

NON-TREATMENT

UCI 98-41 (UCI)

PI: Ahlering
 Coord: J. Tran
 Accrual 2720/3380

UCI 17-07 (UCI)

PI: Ahlering
 Coord: J. Tran
 Accrual 1061/1875

UCI 00-55 (UCI)

PI: Ahlering
 Coord: L. Huynh
 Accrual 429/450

UCI 17-40 (UCI)

PI: Uchio
 Coord: P. Duffy
 Accrual 975/1027

UCI 23-223 (Curium)

Ph3 Cu64 PSMA I&T PETCT for newly dx prostate patients

PI: Uchio
 Coord: TBD
 Accrual 6/10

UCI 23-159

PI: Cozen
 Coord: TBD
 Accrual 0/240

UCI 24-60 (UCI)

Qualitative semi-structured interviews

PI: Hoyt
 Coord: TBD
 Accrual 15/20

UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Feinstein
 Coord: TBD
 Accrual 21/50

UCI 25-31 (UCI)

QOL and cognitive effects of estradiol patch and darolutamide combination therapy

PI: Rezazadeh
 Coord: TBD
 Accrual 0/50



NON-TREATMENT

UCI 24-128 (UCI)

Questionnaires, counseling, saliva collection

PI: Hoyt
Coord: TBD
Accrual 25/100

UCI 24-185 (HistoSonics)

GE LOGIQ E10s US, CT, and MRI

PI: Uchio
Coord: A.Macaraeg
Accrual 4/10

UCI 25-54 (UCI)

64Cu-SAR-bisPSMA Positron Emission Tomography

PI: Uchio
Coord: A.Macaraeg
Accrual 0/20

UCI 23-137

Impact of Intraoperative ICG Use During Robotic-Assisted Radical Prostatectomy on Functional Outcomes

PI: Lee
Coord: J. Go
Accrual 52/400



RT

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: A.Macaraeg

Accrual 1/10

NRG GU013

Arm 1: SBRT (ultrahypofractionation) 5 fractions

Arm 2: Conventional or moderate hypofractionation 20-45 fractions

PI: Hong

Coord: A.Macaraeg

Accrual 3/10

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 16/25

UCI 23-119 (Merck)

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

PI: Rezazadeh
 Coord: J.Go
 Accrual 7/9

UCI 23-204 (TELIX)

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

PI: Srinivas
 Coord: A.Castro
 Accrual 1/10

UCI 24-79 (Amgen)

Phase 3 Study of Xaluritamig vs Cabazitaxel or Second ARDT in Subjects With mCRPC previously Treated With Chemotherapy

PI: Rezazadeh
 Coord: A. Raad
 Accrual 4/10

SWOG S1802

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

PI: Gin
 Coord: N.Arechiga
 Accrual 2/10

UCI 24-140A (Merck)

Phase 1/2 umbrella substudy of MK-2400-U01: ifinatamab deruxtecan (I-DXd)-based treatment combinations or I-DXd alone

PI: Mar
 Coord: A.Macaraeg
 Accrual 0/7



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

Ph1 Dose Escalation and Expansion Study evaluating Safety, Tolerability and Anti-tumor Activity of [225Ac] Ac-FL-020, an anti-PSMA Radioconjugate (RDC)

PI: Srinivas
Coord: A. Macaraeg
Accrual: 0/10

UCI 24-158

A Phase III, Open-Label Study of Ifinatamab Deruxtecan Versus Docetaxel in Participants with Metastatic Castration-Resistant Prostate Cancer (mCRPC) (IDeate-Prostate01)

PI: Rezazadeh
Coord: TBD
Accrual: 0/10

UCI 25-01

A Phase I and Phase II, Multi-Center, Open-Label Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Preliminary Evidence of Antitumor Activity of INV-9956 in Adult Patients With Advanced Metastatic Castration Resistant Prostate Cancer

PI: Uchio
Coord: C. Thao
Accrual: 0/8



MUTATION-SPECIFIC

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: A. Raad
Accrual: 4/5

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

Alliance A032102

Arm A: Valemetostat Tosylate(3201b)
Arm B: Cabazitaxel + Carboplatin
Arm C: Cabazitaxel or AR Targeting Agent or Lutetium Lu 177
PI: Rezazadeh
Coord: J. Go
Accrual 0/5



SINGLE LINE OF THERAPY

UCI 25-73 (Novartis)

Phase 2 comparing ^{177}Lu + ARPI vs. ^{177}Lu in first-line treatment of PSMA-positive mCRPC

PI: Rezazadeh

Coord: TBD

Accrual: 0/40



NON-TREATMENT

UCI 13-03 (UCI)

Office-Based Percutaneous Ultrasound-Guided Renal Biopsy

PI: Landman

Coord: R. Yoon

Accrual: 14/225

ADJUVANT

1L

UCI 22-130 (VUMC)

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

PI: Mar
Coord: A. Castro
Accrual 7/9

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

NRG GU012

Ph2 SABR for metastatic unresected RCC
Standard Immunotherapy vs. SABR to primary (52Gy in 3 fracs) + Standard Immunotherapy

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

MULTIPLE LINES OF THERAPY

S1931

Immunotherapy-Based Combination Therapy
With or Without Cytoreductive Nephrectomy for
Metastatic RCC

PI: Mar
Coord: TBD
Accrual /10



NON-INVASIVE

Ta, T1, CIS

UCI 24-47 (Ferring)

Nadofaragene Firadenovec vs. observation
in IR NMIBC

PI: Uchio
Coord: A. Marinkovic
Accrual 0/5

Low Grade

UCI 21-37 (Steba)

PI: Uchio
Coord: TBD
Accrual: 2/5

Unspecified

UCI 24-139 (CG Oncology)

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

High-Risk

UCI 22-69 (enGene)

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

UCI 25-02

UGN-101 instillation for LG-UTUC

PI: Yaacoub
Coord: TBD
Accrual: 0/5

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: Uchio
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 23/30

UCI 23-59

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

PI: Mar
 Coord: J. Wang
 Accrual 4/23

NRG-GU015

Phase III Adaptive Radiation for MIBC: Radiosensitizing chemotherapy

PI: Feinstein
 Coord: TBD
 Accrual 0/5

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 4/5

UCI 24-46(Ferring)

Phase 3 intravesical nadofaragene firadenovec alone or w/ chemotherapy (Gem and Doce) or Immunotherapy (Pembrolizumab) in patients with BCG Unresponsive NMIBC

PI: Uchio
Coord: TBD
Accrual 0/5

UCI 24-191 (Daiichi)

Phase 2/3 Dato-DXd + carboplatin or cisplatin vs. Gemcitabine + + Carboplatin or Cisplatin in Ia/mUC who progressed during or after EV+Pembro

PI: Rezazadeh
Coord: TBD
Accrual 0/5

UCI 25-184

An Interventional, Phase 1b/2, Open-Label Study to Investigate the Tolerability, Antitumor Activity, and Pharmacokinetics of PF-08634404 Monotherapy or in Combination With Enfortumab Vedotin

PI: Mar
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

UCI 24-159 (Eli Lilly)

Ph1a LOXO-435 monotherapy
Ph1b LOXO-435 +/- pembro +/- EV
B3 Pembro + LOXO-435
B5 Pembro + EV + LOXO-435

PI: Mar
Coord: TBD
Accrual 0/5

UCI 25-183

Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Vepugratinib Combined with EV/Pembro in Adults with an FGFR3 Genetic Alteration.

PI: Mar
Coord: TBD
Accrual 0/5



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 25-44 (UCI)

ctDNA using Northstar-Response and Northstar-
Select for TRM in GU malignancies with bone or
LN metastases

PI: Yazdanpanah
Coord: TBD
Accrual 0/24



MUTATION-SPECIFIC

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 23-66 (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: S. Fernandez
Accrual: 2/5



ALL-COMERS

NRG CC014

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

PI: Harris
Coord: N. Arechiga
Accrual: 1/20

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

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: TBD
Accrual: 0/4

NRG BN013 **

Phase III: Single fraction Stereotactic Radiosurgery (SRS) vs Fractionated Stereotactic Radiosurgery (FSRS)

PI: Simon
Coord: Daniel Na
Accrual: 0/5 (open in Dec 2024)

UCI 25-186

First-In-Human, Open-Label, Dose Escalation Trial with Expansion Dose Cohorts to Evaluate the Safety, Pharmacokinetics and Efficacy of GEN1106 in Participants with Urothelial, Breast, Lung and Head and Neck Carcinomas

PI: Rezazadeh
Coord: TBD
Accrual: 0/5



ALL-COMERS

ETCTN-10558

Triapine + 177Lu-dotatate vs. 177Lu dotatate
alone for well-differentiated somatostatin
receptor-pos NETs

PI: Dayyani
Coord: H. Nguyen
Accrual: 3/3



ALL-COMERS

UCI 25-14

Antineoplastic Therapy

PI: Rezazadeh
Coord: TBD
Accrual: 2/50

UCI 25-83

Mobile Health Intervention to Improve
Adherence to Oral Anticancer Therapy

PI: Sadigh
Coord: TBD
Accrual: 0/60

UCI 24-176 (ARSENAL)

Antineoplastic Therapy

PI: Mar
Coord: J. Wang
Accrual: 0/5