

# Genitourinary Disease-Oriented Team

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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 61/175



## NON-TREATMENT

### UCI 98-41 (UCI)

PI: Ahlering  
Coord: J. Tran  
Accrual 2708/3380

### 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 5/10

### UCI 23-159

PI: Cozen  
Coord: TBD  
Accrual 0/240

### UCI 24-60 (UCI)

Qualitative semi-structured interviews

PI: Hoyt  
Coord: TBD  
Accrual 14/20

### UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Seyedin  
Coord: TBD  
Accrual 0/50

### 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 16/100

### 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

### UCI 23-137

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

PI: Lee  
Coord: J. Go  
Accrual 51/400



## 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: 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 2/10

## 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. Wang  
Accrual 6/9

### 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 4/10

### SWOG S1802

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

PI: Gin  
Coord: J. Wang  
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: TBD  
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

### 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. Dimisuy  
Accrual 0/8

### 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

### 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: 2/5



## SINGLE LINE OF THERAPY

### UCI 25-73 (Novartis)

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

PI: Rezazadeh  
Coord: TBD  
Accrual: 0/40



## NON-TREATMENT

## ADJUVANT

### UCI 13-03 (UCI)

Office-Based Percutaneous Ultrasound-Guided Renal Biopsy

PI: Landman

Coord: R. Yoon

Accrual: 14/225



Open to Accrual



Low Accruing



Pending Activation/Suspended

## 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

### 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

### 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: J. Wang

Accrual 0/5



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 20/30

### 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 la/mUC who progressed during or after EV+Pembro

PI: Rezazadeh  
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





## 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)



## 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

### ETCTN-10558

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

PI: Dayyani  
Coord: H. Nguyen  
Accrual: 2/3



## ALL-COMERS

### UCI 24-28

Surveys for all newly diagnosed cancer pts

PI: Sadeghi  
Coord: R. Kao  
Accrual: 91/90

### 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

### UCI 24-176 (ARSENAL)

Antineoplastic Therapy

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