

Genitourinary Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

- 2025

Open to Accrual
 Low Accruing
 Pending Activation/Suspended

- UCI 25-32 (Mar): A Phase III, Randomized, Open-label Study of Belzutifan + Zanzalintinib Versus Cabozantinib for the Treatment of Participants with Locally Advanced or Metastatic RCC who Experienced Disease Recurrence During or After Prior Adjuvant Anti-PD-1/L1 Therapy (LITESPARK-033)
- UCI 25-33 (Mar): A Multicenter, Double-blind, Randomized Phase III Study of Belzutifan + Zanzalintinib Versus Belzutifan + Placebo in Participants with Locally Advanced or Metastatic RCC that have Progressed on or after both PD-1/L1 and VEGF-TKI Therapies in Sequence or in Combination (LITESPARK-034)
- UCI 25-99 (Gin; IIT): Single Dose CYTALUX (Pafolacianine, OTL38) for Intraoperative Imagein of Prostate Cancer - a Pilot Study
- UCI 25-100 (Daneshvar; IIT): Utilization of Flotufolastat 18F PET for Post-Focal Therapy Prostate Cancer Evaluation
- UCI 25-130 (Uchio): An Open-Label, International, Multicenter Phase II Study to Evaluate the Efficacy and Safety of Intravesical T3011 Injection in Participants with BCG-Unresponsive High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) or BCG-Exposed, Chemotherapy Unresponsive Intermediate High-Risk NMIBC
- UCI 25-134 (Rezazadeh): A Phase Ib, 2-part, Multicenter, Single-arm, Open-label Study to Evaluate the Safety and Efficacy of a Nectin-4 Radiopharmaceutical ([225Ac]Ac-AKY-1189) in Patients with Previously Treated Locally Advanced or Metastatic Solid Tumors
- UCI 25-160 (Shahait): DIRECT-AI: Decision Impact Registry for Evaluation of Clinical Treatment with ArteraAI in Prostate Cancer

- 2026
 - A032304 (Yazdanpanah): Radioligand Efficacy Comparison by Initial PSA-Response Outcome in Metastatic CRPC with Lutetium 177Lu PSMA RLT (RECIPROCAL)
 - UCI 26-19 (Exempt; Uchio): Validation of the Genomic Prostate Score (GPS) as a Predictive Biomarker of Oncologic Outcomes in Men with High-Risk Prostate Cancer (NCCN Guidelines v1.2025)
 - UCI 26-06 (EAP; Exempt; Daneshvar): ResQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer



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 78/175

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



OBSERVATIONAL/RETROSPECTIVE

UCI 98-41 (UCI)

Outcomes and Assessment of Prostate Cancer

PI: Ahlering
Coord: J. Tran
Accrual 2813/3380

UCI 17-07 (UCI)

(PROVOQ): Post-Radical Prostatectomy Outcome Assessment

PI: Ahlering
Coord: J. Tran
Accrual 1164/1875

UCI 17-40 (UCI)

Precision Medicine for Early Prostate Cancer

PI: Uchio
Coord: A. Macaraeg/D. Huttar
Accrual 975/1027

UCI 00-55 (UCI)

Retrospective Evaluation of Prostate Cancer Clinical and Pathological Outcomes

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

UCI 23-159 (UCI)

Prostate cancer and HPV

PI: Cozen
Coord: TBD
Accrual 0/240

UCI 24-60 (UCI)

Qualitative semi-structured interviews

PI: Hoyt
Coord: TBD
Accrual 16/20



DIAGNOSTIC

UCI 23-223 (Curium)

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

PI: Uchio

Coord: T. Cao, RN

Accrual 6/10

UCI 25-54 (Clarity Pharmaceuticals)

SUSPENDED

64Cu-SAR-bisPSMA PET after biochemical recurrence

PI: Uchio

Coord: A. Stelter

Accrual 15/20

UCI 25-159 (UCI)

CTDNA-PSMA-BCR: A Single-Arm Trial of Circulating Tumor DNA-Guided Treatment Escalation and De-escalation in Biochemical Recurrent Prostate Cancer

PI: Shahait

Coord: TBD

Accrual 0/100

UCI 25-185 (Clarity Pharmaceuticals)

64Cu-SAR-bisPSMA PET prior to RARP

PI: Uchio

Coord: TBD

Accrual 0/10



SUPPORTIVE CARE/QUALITY OF LIFE

UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Feinstein
Coord: TBD
Accrual 23/50

UCI 24-128 (UCI)

Questionnaires, counseling, saliva collection

PI: Hoyt
Coord: TBD
Accrual 42/100

UCI 25-31 (UCI)

QOL and cognitive effects of estradiol patch and darolutamide combination therapy for HSPC

PI: Rezazadeh
Coord: TBD
Accrual 0/50



RT

NRG GU013

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

PI: Hong
Coord: A.Macaraeg/J. Pon
Accrual 6/10

SURGERY

UCI 23-137 (UCI)

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

PI: Lee
Coord: J. Go
Accrual 69/400

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: J. Go
 Accrual 17/25

UCI 23-119 (Merck)

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

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

UCI 23-204 (TEPIX)**SUSPENDED**

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

PI: Srinivas
 Coord: A. Castro/A. Kote
 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 5/10

SWOG S1802

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

PI: Gin
 Coord: J. Go
 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: TBD

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)

SUSPENDED

PI: Srinivas

Coord: R. Enaworu

Accrual: 3/10

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: A. KoteAccrual: 1/8

UCI 25-01

INV-9956 (CYP11A1 inhibitor) in mCRPC

PI: Uchio

Coord: C. Thao/A. Stelter

Accrual: 0/4

CCTG-PR26

TRIPLE-SWITCH: Docetaxel + ARPI for mCRPC and suboptimal PSA response

PI: Yazdanpanah

Coord: A. Kote

Accrual: 0/5

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio

Coord: A. Stelter

Accrual: 1/4



MUTATION-SPECIFIC

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



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 8/9

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: 1/5

MULTIPLE LINES OF THERAPY

SWOG S1931

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

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

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: A. Stelter
Accrual: 1/4

UCI 25-158

Orellanine treatment in patients with metastatic clear-cell or papillary renal cell carcinoma

PI: Mar
Coord: TBD
Accrual 0/3



NON-INVASIVE: LOW GRADE

Upper Tract

UCI 24-47 (Ferring Pharm)

Nadofaragene Firadenovec vs. observation in **IR** NMIBC
PI: Uchio
Coord: A. Marinkovic
Accrual 2/5

UCI 25-02 (UroGen)

UGN-101 instillation for LG-UTUC

PI: Uchio
Coord: T. Cao, RN
Accrual: 0/5

NON-INVASIVE – HIGH GRADE

UCI 22-69 (enGene)

EG-70 for BCG-Unresponsive NMIBC and HR BCG-naïve or received incomplete treatment

PI: Uchio
Coord: T. Cao, RN
Accrual 1/5

UCI 24-47 (Ferring)

Nadofaragene Firadenovec vs. observation in IR NMIBC

PI: Uchio
Coord: A. Marinkovic
Accrual 2/5

Alliance A032303

Gemcitabine Alternating with BCG vs BCG alone for recurrent HG NMIBC

PI: Daneshvar
Coord: J. Pon
Accrual 1/10

UCI 23-206

TARA-002 in HG NMIBC
Cohort A: CIS +/- Ta/T1 BCG naïve/exposed
Cohort B: CIS +/- Ta/T1 BCG unresponsive

PI: Uchio
Coord: A. Marinkovic
Accrual 4/12

UCI 24-139 (CG Oncology)

Cretostimogene Grenadenorepvec in HR NMIBC

PI: Uchio
Coord: A. Marinkovic
Accrual 0/10

UCI 24-46 (Ferring)

Nadofaragene firadenovec +/- gemcitabine and docetaxel or pembrolizumab in HG BCG-unresponsive NMIBC

PI: Uchio
Coord: A. Marinkovic
Accrual 1/5

UCI 25-86 (ImmunityBio)

SUSPENDED

BCG + ALT-803 (N-803) for NMIBC

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/A. Kote
Accrual 26/30

UCI 23-59

Adjuvant Sacituzumab Govitecan Plus Nivolumab in ctDNA Positive Patients

(USC and Hoag not yet open)

PI: Mar
Coord: A. Castro
Accrual 4/23

NRG-GU015

Phase III Adaptive Radiation for MIBC: Radiosensitizing chemotherapy

PI: Feinstein
Coord: J. Pon
Accrual 1/5

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: 4/5

ALL-COMERS

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
 Coord: A. Stelter
 Accrual: 1/4

UCI 22-128 (Merck)

MK-2140 (Zilovertamab Vedotin) IV D1/D8 Q3W

PI: Rezazadeh
 Coord: A. Raad
 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 5/8

ECOG-EA8231

A Phase III Randomized Trial of Pembrolizumab
 in Combination with Sacituzumab Govitecan vs
 Standard of Care in Anti-PD(L)1-Resistant
 Advanced Urothelial Cancer

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

UCI 24-191 (Daiichi Sankyo)

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: A. Castro
 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 5/8

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: A. Kote
Accrual 2/5

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 0/7



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: 37/50

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: 3/5



ALL-COMERS

NRG CC014

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

PI: Harris
Coord: N. Arechiga
Accrual: 4/20

UCI 22-26 (Cosmo Technologies)

SUSPENDED

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: B. Nguyen
Accrual: 11/12

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: A. Stelter
Accrual: 1/4

NRG BN013

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

PI: Simon
Coord: S. Beltran
Accrual: 1/5

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



ALL-COMERS

UCI 25-14

Antineoplastic Therapy

PI: Rezazadeh
Coord: J. Seneriches
Accrual: 6/50

UCI 25-83

Mobile Health Intervention to Improve
Adherence to Oral Anticancer Therapy

PI: Sadigh
Coord: TBD
Accrual: 31/35

UCI 24-176 (Daiichi Sankyo))

Evaluate Efficacy and Safety of Raludotatug
Deruxtecan (R-DXd) in Participants with
Advanced/Metastatic Solid Tumors

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