

Genitourinary Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

- 2025

- 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 25-130 (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
 - 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)



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 82/175

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 13/125



OBSERVATIONAL/RETROSPECTIVE

UCI 98-41 (UCI)

Outcomes and Assessment of Prostate Cancer

PI: Ahlering
Coord: J. Tran
Accrual 2841/3380

UCI 17-07 (UCI)

(PROVOQ): Post-Radical Prostatectomy Outcome Assessment

PI: Ahlering
Coord: J. Tran
Accrual 1193/1875

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 20/20

UCI 26-89

Mobile PSA Initiative Outcomes

PI: Daneshvar
Coord: TBD
Accrual : 0/50

UCI 26-45(UCI)

Health, Digital, and Numerical Literacy and Prostate-Related Knowledge in Men With Elevated PSA or With Prostate Cancer on Active Surveillance

PI: Shahait
Coord: TBD
Accrual 16/375

UCI 26-19

Validation of (GPS) as a Predictive Biomarker for Outcomes in Men with High-Risk Prostate Cancer

PI: Uchio
Coord: TBD
Accrual : 0/999



DIAGNOSTIC

UCI 25-185 (Clarity Pharmaceuticals)

64Cu-SAR-bisPSMA PET prior to RARP

PI: Uchio
 Coord: Mandi
 Accrual 2/10

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 25-100

Utilization of Flotufolastat 18F PET for Post-
 Focal Therapy Prostate Cancer Evaluation

PI: Daneshvar
 Coord: A.Raad
 Accrual 0/50



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 68/100

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: J. Pon

Accrual 10/15

SURGERY

UCI 23-137 (UCI)

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

PI: Lee

Coord: M.Barnachea

Accrual 83/400



MULTIPLE LINES OF THERAPY

ETCTN 10301

SUSPENDED

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 8/9

UCI 23-204 (TEPIX)

SUSPENDED

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

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

UCI 26-132 (TULMISTAR)

Phase II/III, Randomized, Open-label,
Tulmimetostat in Combination with Androgen
Receptor Pathway Inhibitor versus
Investigator's Choice Standard in mCRPC

PI: Mar
Coord: TBD
Accrual 0/5

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:
ifinatumab deruxtecan (I-DXd)-based
treatment combinations or I-DXd alone

PI: Mar
Coord: A. Castro
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: J.Pon
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: R. Enaworu
Accrual: 4/10

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. Kote
Accrual: 2/8

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: 3/4



MULTIPLE LINES OF THERAPY

A032304

Radioligand Efficacy Compare by PSA-Response Outcome in MetCRPC w/Lutetium 177Lu PSMA RLT (RECIPROCAL)

PI: Yaz
Coord: J. Go
Accrual 3/8 (Step 1)

UCI 25-18

AcTFIRST : AAA817+ARPI Versus Standard of Care in Adult Participants with PSMA-positive mCRPC

PI: Rezazadeh
Coord: J. Pon
Accrual 0/5

UCI 26-81

First-in-Human VIR-5500 (AMX-500) in Participants With Prostate Cancer

PI: Rezazadeh
Coord: A. Kote
Accrual 0/6

UCI 26-91 JANX007

A PHASE 1 OPEN-LABEL, MULTICENTER STUDY OF JANX007 ADMINISTERED SUBCUTANEOUSLY IN PARTICIPANTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

PI: Uchio
Coord: TBD
Accrual 0/5

UCI 26-92 JANX007

A Phase 2a Multicenter Dose Escalation and Dose Optimization Study of SYNC-T Therapy SV-102 for Patients with mCRPC

PI: Uchio
Coord: TBD
Accrual 0/5



MUTATION-SPECIFIC

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 8/9

SINGLE LINE OF THERAPY



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

NON-TREATMENT

UCI 13-03 (UCI)

Office-Based Percutaneous Ultrasound-Guided Renal Biopsy

PI: Landman
Coord: R. Yoon
Accrual: 14/225

NEOADJUVANT

ETCTN 10743

Pilot Phase II Trial Evaluating Safety and Feasibility of Neoadjuvant Botensilimab and Balstilimab in ccRCC (NEORoBOT)

PI: Daneshvar
Coord: TBD
Accrual:

ADJUVANT

■ Open to Accrual

■ Low Accruing

■ Pending Activation/Suspended

1L

MULTIPLE LINES OF THERAPY

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

SWOG S1931

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

PI: Mar
Coord: A. Kote
Accrual 5/8

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: A. Stelter
Accrual: 2/4

SWOG S2419

Ph 3 double blinded trial of immune based TRIAL
live MO-03 or Placebo for advanced ccRCC

PI: Yazdanepaneh
Coord: A.Kote
Accrual 1/7

UCI 25-158

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

PI: Mar
Coord: J.Go
Accrual 1/5



1L

UCI 26-111

Open label First-in-Human, Phase 1/2 Study of NEO-811 in Subjects With Locally Advanced or Metastatic Non-Resectable ccRCC

PI: Yazdanepaneh
Coord: TBD
Accrual 0/10

MULTIPLE LINES OF THERAPY

UCI 26-134

Phase II Study of **Belzutifan** in Advanced non-clear cell RCC (BEAR)

PI: Mar
Coord: TBD
Accrual 0/5



NON-INVASIVE: LOW GRADE

UCI 24-47 (Ferring Pharm)

Nadofaragene Firadenovec vs. observation in IR NMIBC
PI: Uchio
Coord: T. Cao
Accrual 3/5

UCI 26-76 (UroGen)

UGN 501 administered intravesically with recurrent (NMIBC)
PI: Uchio
Coord: TBD
Accrual: 0/999

UCI 26-06

ResQ132EX-NMIBC: Expanded Access Use of Recombinant
Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder
Cancer

PI: Daneshvar
Coord: A. Stelter
Accrual 4/5

UCI 26-130 (Relmada)

A Phase 3 Study Evaluating the Efficacy and Safety of NDV-01 in
Participants with Non-muscle Invasive Bladder Cancer (RESCUE)

PI: Uchio
Coord: TBD
Accrual: 0/5

Upper Tract

UCI 25-02 (UroGen)

UCI 25-02

UGN-101 instillation for LG-UTUC

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



NON-INVASIVE: LOW GRADE

UCI 26-158

Ph3, Randomized, Double-Blind, Placebo-Controlled,
Dabogratinib versus Placebo as an Adjuvant Therapy in
Participants with FGFR3 Altered **Low Grade**, Intermediate Risk
NMIBC

PI: Uchio
Coord: TBD
Accrual:

Upper Tract



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: T. Cao, RN
Accrual 3/5

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. Raad
Accrual 4/12

UCI 24-139 (CG Oncology)

Cretostimogene Grenadenorepvec in HR NMIBC

PI: Uchio
Coord: TBD
Accrual 0/10

UCI 26-93

Randomized Study to Evaluate the Efficacy and Safety of Intravesical TARA-002 Compared with Investigator's Choice of Intravesical Chemotherapy in Participants with BCG-naïve High-Grade Non-Muscle Invasive Bladder Cancer

PI: Uchio
Coord: TBD
Accrual: 0/5

UCI 24-46 (Ferring)

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

PI: Uchio
Coord: T. Cao
Accrual 2/5

NRG GU-014

RANDOMIZED PHASE II TRIAL OF PEMBROLIZUMAB AND RADIATION VS. RADIATION AND CONCURRENT CHEMOTHERAPY FOR HIGH-GRADE T1 BLADDER CANCER (PARRC TRIAL)

Coord: M. Barnachea
PI: Feinstein
Accrual: 0/11

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 30/31

UCI 23-59

Adjuvant Sacituzumab Govitecan Plus Nivolumab in ctDNA Positive Patients

(USC and Hoag not yet open)

PI: Mar
Coord: A. Castro
Accrual 5/27

NRG-GU015

Phase III Adaptive Radiation for MIBC: Radiosensitizing chemotherapy

PI: Feinstein
Coord: J. Pon
Accrual 3/5

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: J. Go
Accrual: 5/8

UCI 26-73

Enfortumab Vedotin in Combination with Pembrolizumab for patients who are ineligible for or have Elected not to Undergo Cystectomy

PI: Mar
Coord: TBD
Accrual 0/5

UCI 26-74

Enfortumab Vedotin plus Pembrolizumab for Bladder Preservation in Participants with Muscle-invasive Bladder Cancer

PI: Mar
Coord: TBD
Accrual 0/5

ALL-COMERS

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio
 Coord: A. Stelter
 Accrual: 2/4

UCI 22-128 (Merck)

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

PI: Rezazadeh
 Coord: A. Castro
 Accrual 1/3

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 3/5

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

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: J.Pon
 Accrual 0/7

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 7/10

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 3/5



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: Arter

Coord: J. Choe

Accrual: 43/50



ALL-COMERS

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

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: 2/4

UCI 25-153

A Phase I Study of 177LU-IM-3050 in Participants with Advanced Malignancies

PI: Dr. Gupta
Coord: TBD
Accrual: 0/5

UCI 26-157

A Phase 1, Open-label, Multi-center Study of the Safety, Tolerability, and Efficacy of IPH4502 as a Single Agent in Advanced Solid Tumors

PI: Dr. Uchio
Coord: TBD
Accrual: 0/5



ALL-COMERS

UCI 25-14

Antineoplastic Therapy

PI: Rezazadeh
Coord: J. Seneriches
Accrual: 10/50

UCI 24-05

Riluzole PO vs. Placebo PO
Perceived worsening of *cognitive function*

PI: Chan
Coord: Randy Kang
Accrual: 31/59

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