UCI 趙 Chao Family Comprehensive Cancer Center




# Genitourinary Disease-Oriented Team

## Clinical Research Treatment Trial Flowchart

# DOT-Approved, To Be Added

2026

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 83/175

### 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 19/125

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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 25-160
DIRECT-AI: Decision Impact Registry for Evaluation of Clinical Treatment with ArteraAI in Prostate Cancer

PI: Shahait
Coord: TBD
Accrual 0/50

### 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: M.Albia
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 19/375

### UCI 26-19
Validation of (GPS) as a Predictive Biomarker forOutcomes in Men with High-Risk Prostate Cancer

PI: Uchio
Coord: A.Stelter
Accrual : 0/999

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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

### UCI 25-99 (UCI)

Single Dose CYTALUX (Pafolacianine, OTL38) for Intraoperative Image in of Prostate Cancer - a Pilot Study

PI: Gin
Coord: TBD
Accrual 0/10

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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: D.Zoeter
Accrual 71/100

### UCI 25-31 (UCI)

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

PI: Yazdanpaneh
Coord: TBD
Accrual 0/50

# Prostate – Treatment: Localized

Open to Accrual | Low Accruing | Pending Activation/Suspended

## RT

### NRG GU013

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

PI: Hong
Coord: M. Barnachea
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 84/400

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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 23-204 (TELIX)

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

PI: Mar
Coord: A. Castro
Accrual 0/10

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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: 1/5

### 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: 5/10

### 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: 3/8

### 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: 1/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

## MULTIPLE LINES OF THERAPY

### A032304
Radioligand Efficacy Compare y PSA-ResponseOutcome in MetCRPC wLutetium 177Lu PSMA RLT (RECIPROCAL)

PI: Yazdanpaneh
Coord: J. Go
Accrual 4/8 (two on Step 1) b

### 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 10/15

### 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

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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

# Renal – Non-Treatment/Neo/Adjuvant

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: 0/5

## ADJUVANT

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 9/9

### 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

### UCI 24-142 (KaliVir)
VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: A. Stelter
Accrual: 3/4

### 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

## MULTIPLE LINES OF THERAPY

### SWOG S1931
Immunotherapy-Based Combination Therapy With or Without Cytoreductive Nephrectomy for Metastatic RCC

PI: Mar
Coord: A. Kote
Accrual 6/8

### UCI 25-158
Orellanine treatment in patients with metastatic clear-cell or papillary renal cell carcinoma

PI: Mar
Coord: J.Go
Accrual 3/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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

### UCI 25-32

PhIII Open-label Belzutifan + Zanzalintinib vs. Cabozantinib in Advanced RCC w/ dz recurrence during/after prior Adjuvant Anti-PD-1/L1 Therapy (LITESPARK-033)

PI: Mar
Coord: TBD
Accrual 0/8

## MULTIPLE LINES OF THERAPY

### UCI 26-134

Phase II Study of **Be**lzutifan in **A**dvanced non-clear cell **R**CC (BEAR)

PI: Mar
Coord: TBD
Accrual 0/5

### UCI 25-33

PhIII Double-blind Belzutifan + Zanzalintinib vs. Belzutifan + Placebo in Advanced RCC who progressed on/after both PD-1/L1 and VEGF-TKI in sequence or in combo (LITESPARK-034)

PI: Mar
Coord: TBD
Accrual 0/8

Open to Accrual | Low Accruing | Pending Activation/Suspended

## NON-INVASIVE: LOW GRADE

### UCI 24-47 (Ferring Pharm)
Nadofaragene Firadenovec vs. observation in **IR** NMIBC
PI: Uchio
Coord: T. Cao
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: 0/999

### UCI 26-76 (UroGen)
UGN 501 administered intravesically with recurrent (NMIBC)
PI: Uchio
Coord: TBD
Accrual: 0/999

Upper Tract

### UCI 25-02 (UroGen)
### UCI 25-02
UGN-101 instillation for LG-UTUC

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

### UCI 26-06
ResQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer
PI: Daneshvar
Coord: A.Stelter
Accrual 21/25

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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 4/5

### 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)
*SUSPENDED*
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-GU014
PEMBROLIZUMAB AND RADIATION VS. RADIATION AND CONCURRENT CHEMOTHERAPY FOR HIGH-GRADE T1 BLADDER CANCER (PARRC TRIAL)

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

### UCI 25-130
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

PI: Uchio
Coord: TBD
Accrual: 0/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

## MUSCLE INVASIVE

### UCI 26-137

LIFT: Lifestyle Improvement to Facilitate Tumor-Immunity

PI: Dr. Deng
Coord: TBD
Accrual: 0/30

### UCI 23-59

Adjuvant Sacituzumab Govitecan Plus Nivolumab in ctDNA Positive Patients

(USC and Hoag not yet open)

PI: Mar
Coord: A. Castro
Accrual 6/27

### 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: 6/8

### 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: J.Go
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

Open to Accrual | Low Accruing | Pending Activation/Suspended

## ALL-COMERS – PREVIOUSLY UNTREATED

### 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: J.Go
Accrual 0/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

## ALL-COMERS – PREVIOUSLY TREATED

### UCI 24-142 (KaliVir)
VET3-TGI +/- Pembrolizumab

PI: Uchio
Coord: A. Stelter
Accrual: 3/4

### UCI 22-128 (Merck)
MK-2140 (Zilovertamab Vedotin) IV D1/D8 Q3W

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

### UCI 25-134
Safety and Efficacy of a Nectin-4 Radiopharmaceutical ([225Ac]Ac-AKY-1189) in Patients with Previously Treated Locally Advanced or Metastatic Solid Tumors

PI: Rezazadeh
Coord: TBD
Accrual 0/5

### 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 + carboplation 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: J.Go
Accrual 0/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

## BIOMARKER/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 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

# Basket Trials – Prevention/Non-Treatment

Open to Accrual | Low Accruing | Pending Activation/Suspended

## 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

# Basket Trials – Mutation-Specific

## 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

Open to Accrual | Low Accruing | Pending Activation/Suspended

# Basket Trials – All-Comers

## 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: 3/4

### UCI 25-153

**SUSPENDED**

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

Open to Accrual | Low Accruing | Pending Activation/Suspended

# Non-Treatment – All Comers

## 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: M.Phan
Accrual: 34/59

### 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