Inaugural Southern California Genitourinary Cancer Research Forum

Panel: Bladder Studies (NMIBC; MIBC; Metastatic, 1st; Metastatic; salvage)

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Speakers:

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Disclosures

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This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

Disclosures

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This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

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This presentation has been peer-reviewed and no conflicts were noted.

The off-label/investigational use of Durvalumab, Tremelimumab, Tiragolumab, Atezolizumab, and Enfortumab vedotin will be addressed.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

- *Difference in bladder cancer incidence between men and women.*
- *Implicit biases in clinical trial enrollment.*

Non-Muscle Invasive Bladder Cancer (NMIBC)

Bladder Cancer - NMIBC

Study Title	Study Design	Other Details
NCT04640623	Efficacy and Safety of TAR-200 in Combination With Cetrelimab, TAR-200 Alone, or Cetrelimab Alone	• HR-NMIBC. • Unresponsive to BCG, not candidates for RC. • **Cohorts 1-3:** closed • **Cohort 4:** Papillary disease only (accruing)
NCT05085977	Intravesical TARA-002 in HG-NMIBC.	• Dose escalation study, one treatment arm. • Treatment naïve, unable to receive BCG. • Safety and efficacy of TARA-002.
NCT06111235	Adjuvant Cretostimogene Grenadenorepvec (CG) for Treatment of Intermediate Risk NMIBC Following TURBT	• CG vs observation after removal of all visible lesions in TURBT.
NCT05538663	BCG naïve patients with NMIBC that receive GEMDOCE will show non-inferior EFS compared to SOC BCG therapy.	• No prior intravesical therapy. • NMIBC
NCT02625961	Pembro +/- coformulations for HR-NMIBC that is unresponsive to BCG.	• HR-NMIBC. • Unresponsive to BCG/ • Ineligible for RC.

Bladder Cancer – NMIBC

Keck Medicine of USC

SunRISe-1

NCT04640623

Phase 2b

Key Eligibility Criteria

- Confirmed HR-NMIBC, CIS] or Tis, with or without papillary disease or papillary disease only within 12 months of completion of BCG therapy.
- Papillary disease fully resected.
- Ineligible for or elected not to undergo radical cystectomy.
- BCG-unresponsive high-risk NMIBC after treatment with adequate BCG therapy.
- ECOG ≤2

Stratification

- Concomitant papillary disease (presence/absence).

R (2:1:1) N = 200

- **TAR-200** intraurethral Q3W for 3 months, then Q12W for 2 years + **Cetrelimab IV** Q3W for 18 months.
- **TAR-200** intraurethral Q3W for 3 months, then Q12W for 2 years
- **Cetrelimab** IV Q3W for 18 months.
- **TAR-200** intraurethral Q3W for 3 months, then Q12W for 2 years (papillary disease only)

Follow up 5 years.

- **TAR-200:** releases gemcitabine in the bladder stromal cells.
- **Cetrilimab:** mAB anti-PD1.

Endpoints:
Primary: CR.
Secondary: DOR, OS, AEs, QOF, Concentration of Gemcitabine.

Bladder Cancer – NMIBC

Keck Medicine of USC

NCT05085977

ADVANCED-1

Phase 1b

Key Eligibility Criteria

- Confirmed, high-grade Ta or CIS (including CIS with concomitant Ta) urothelial cell carcinoma of the bladder.
- Treatment naïve, unable to obtain BCG, received at least one dose of BCG, or at least one dose of intravesical chemotherapy.

→ N = 18 →

TARA-002
intraurethral **e**scalating dose 10 KE → 20 KE → 40 KE with 6 weekly intravesical doses.

→

Follow Up

- Until MTD or RP2D have been achieved.
- If MTD not achieved, additional cohorts with higher than 40 KE may be explored.

- **TARA-002:** a lyophilized biological preparation containing cells of *Streptococcus pyogenes.*

Endpoints:
Primary: MTD, DLAEs, DLT, RP2D.
Secondary: N/A.

Bladder Cancer – NMIBC

Keck Medicine of USC

NCT06111235

PIVOT-006

Phase 3

Key Eligibility Criteria
- Pathologically confirmed IR-NMIBC.
- Recurrent LG Ta within 12 months of prior LG or HG (HG Ta ≤ 3 cm) tumor.
- Solitary LG Ta >3 cm tumor.
- Multifocal LG Ta tumors.
- Primary and solitary HG Ta ≤3 cm tumor.
- LG T1 tumor.
- All visible disease removed by TURBT.

Stratification
- Perioperative chemo (yes/no).
- HG vs. LG.
- Geography.

R (1:1)
N = 426

Cretostimogene intraurethral after TURBT with induction course and then quarterly maintenance courses.

Observation after TURBT

Follow up 3 years.

Endpoints:
Primary: RFS (Time frame of 51 months).
Secondary: RFS, AEs (At 12 and 24 months, time frame of 52 months).

- **Cretostimogene Grenadenorepvec (CG):** an oncolytic adenovirus designed to replicate in and kill cancer cells.

Bladder Cancer - NMIBC

UC San Diego
SCHOOL OF MEDICINE

NCT05538663

BRIDGE

Phase 3

Key Eligibility Criteria

- Histologically confirmed HG-NMIBC on TURBT.
- All visible papillary tumor resected.
- No prior intravesical therapy for bladder cancer.
- HG T1 disease must have undergone restaging TURBT.

Stratification

- Pure CIS.
- Pure papillary disease.
- Concurrent CIS and papillary disease.

→ **TURBT** → R (1:1) N = 870

→ Gemcitabine intravesical for 6 consecutive weeks, then monthly for 2 years
+
Docetaxel intravesical for 6 consecutive weeks, then monthly for 2 years

→ BCG intravesical for 6 consecutive weeks, then weekly for 3 consecutive weeks at months 3, 6, 12, 18, 24, 30 and 36.

→ Follow up 2 years.

- **Gemcitabine:** inhibits the transition from the G1-S phase, inhibiting DNA synthesis.
- **Docetaxel:** inhibits microtubule depolymerization and attenuates effects of bcl-2 and bcl-xL gene expression, promoting cell death.

Endpoints:
Primary: EFS.
Secondary: QOL, CFS, PFS.

Bladder Cancer - NMIBC

UCLA Health

KEYNOTE-057

Phase 2

NCT02625961

Key Eligibility Criteria
- Confirmed HR-NMIBC.
- Fully resected disease at entry.
- BCG unresponsive.
- Ineligible for RC.
- ECOG ≤2

N = 320

Cohort A: Pembrolizumab IV 200 mg Q3W up to 24 months for patients with CIS with/without papillary tumors.

Cohort B: Pembrolizumab IV 200 mg Q3W up to 24 months for patients with papillary tumors only.

Cohort C

R (1:1)

Coformulated pembrolizumab 200 mg with vibostolimab 200 mg IV Q3W

Coformulated pembrolizumab 200 mg with favezelimab 800 mg IV Q3W

Cohorts A & B: Discontinue treatment if evidence of HR NMIBC or PD.

Cohort C: Discontinue treatment at 12-weeks if ≥HT T1 , or at ≥ 24 weeks if HR NMIBC or PD.

Follow up 27 months.

- **Pembrolizumab**: a mAB directed against PD-1, thereby impairing its interaction with PD-L1 that would prevent an immune response.
- **Vibostolimab:** a mAB that blocks the interaction between TIGIT and its ligand, activating T cells to troy tumor cells.
- **Favezelimab:** a mAB that blocks LAG-3 and its interaction with its ligand, thereby promoting tumoral cell death.

Endpoints:
Primary: CR, DFS, AEs.
Secondary: CR, DOR, PFS, OS, DFS.

Muscle Invasive Bladder Cancer (MIBC)

Bladder Cancer – MIBC/UTUC

Study Title	Study Design	Other Details
NCT03775265	Chemotherapy and RT with or without atezolizumab in treating patients with localized MIBC.	• Randomized, comparative trial. • Two arms. • TURBT before randomization.
NCT04960709	Efficacy and Safety of Durvalumab with Tremelimumab and EV or Durvalumab with EV	• MIBC. • No prior systemic therapy. • Cisplatin ineligible patients.
NCT05406713	Pembrolizumab in patients with MIBC	• MIBC, cisplatin ineligible. • Evaluate CR, determine subsequent treatment.
NCT05775471	Pembro and EV prior to and after radical nephroureterectomy in HR-UTUC.	• HR-UTUC. • Single Arm.
N/A	Sacituzumab Govitecan and Nivloumab in patients with UC with HR of recurrence post-curative intent surgery that are ctDNA +.	• Multi-center. • Aims to enroll 27 patients over 24 months. • Tissue Tempus xT for biomarker analysis.

Bladder Cancer - MIBC

UC San Diego SCHOOL OF MEDICINE

NCT03775265

INTACT (S/N1806)

Phase 3

Key Eligibility Criteria

- Confirmed T2-T4a N0M0 urothelial carcinoma of the bladder.
- TURBT within 70 days before randomization.
- Radiological staging withing 70 days before randomization.
- No prior urothelial carcinoma or histological variant outside the bladder.
- planning to receive one of the protocol specified chemotherapy regimens.

Stratification

- Clinical Stage T2 vs. T3/T4a
- Chemoregimen cisplatin vs. 5Fu + mitomycicn-C vs. Gemcitabine
- RT field small pelvis vs bladder only.
- ECOG 0-1 vs. 2.

R (1:1)
N = 475

RT 3DCRT or IMRT daily (Mo-Fri) for 7-8 weeks
+
Physicians' choice of chemotherapy

RT 3DCRT or IMRT daily (Mo-Fri) for 7-8 weeks
+
Physicians' choice of chemotherapy
+
Atezolizumab IV D1C1, up to 9 cycles

Follow up 5 years.

Endpoints:
Primary: BI-EFS.
Secondary: OS, mBI-EFS, Biopsy response, CRD, PFS, MFS, CSS, QOF.

- **Atezolizumab**: mAB that binds to PD-L1, impairing interaction with PD-1 and allowing for immune response against tumoral cells.

Bladder Cancer - MIBC

UCLA Health | UCI Health

NCT04960709

VOLGA

Phase 3

Key Eligibility Criteria
- Confirmed MIBC.
- No prior systemic chemotherapy or immunotherapy.
- Medically fit for cystectomy. ECOG ≤2
- Cisplatin ineligible.

Stratification
- Cisplatin eligibility.
- PDL1 (PD-L1+: ≥ 25% tumor membrane or tumor-associated immune cells stained).
- Visceral metastatic.

R (1:1:1) N = 830

- Durvalumab + Tremelimumab + Enfortumab vedotin 3 preop 21-day cycles, followed by 1 cycle of postop tremelimumab and 9 cycles of durvalumab.
- Durvalumab + Enfortumab Vedotin 3 preop 21-day cycles, followed by RC, followed by 9 cycles of Durvalumab.
- Cystectomy with or without approved Adjuvant Therapy.

Follow Up
- Safety and Efficacy evaluates at completion of study by the last patient and at 3 months.
- Time frame up to 3 years.

- **Durvalumab:** mAB that binds to PD-L1, impairing interaction with PD-1 and allowing for immune response against tumoral cells.
- **Tremelimumab:** mAB against CTL4, impairing its immunologic inhibitory mechanism.
- **Enfortumab Vedotin:** antibody drug conjugate that binds to nectin-4 in tumoral cells and stimulates cellular death.

Endpoints:
Primary: pCR, EFS, Safety, AEs.
Secondary: pCR, OS, EFS, OSR, pDS, DSS, QOF, AUC, MFS, tmax.

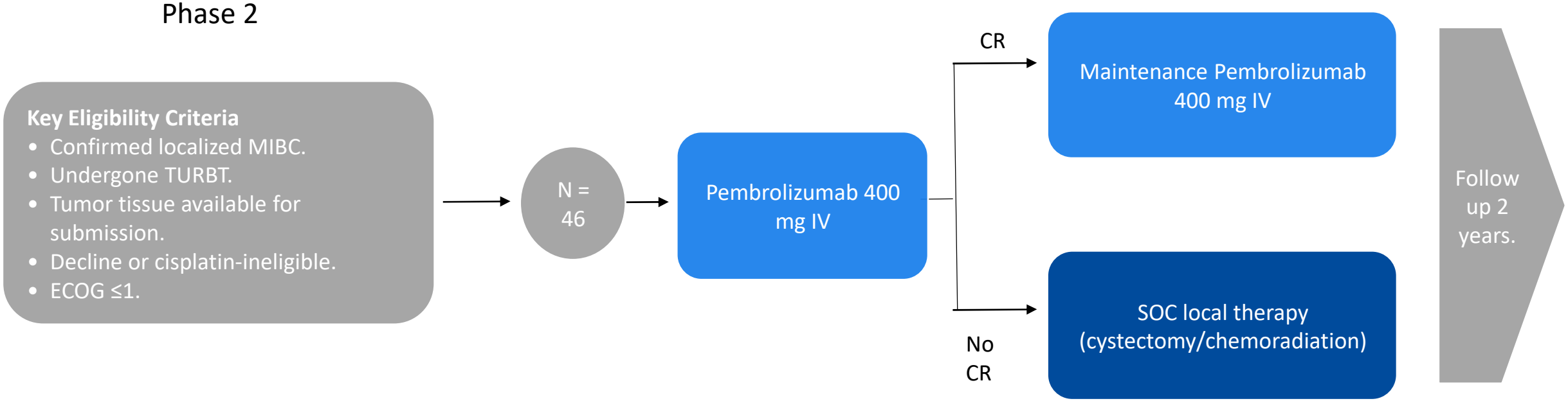
Bladder Cancer - MIBC

City of Hope

NCT05406713

HCRN GU20-444

Phase 2



- **Pembrolizumab**: a mAB directed against PD-1, thereby impairing its interaction with PD-L1 that would prevent an immune response.

Endpoints:
Primary: CRR, Benefit from Tx.
Secondary: MTS, RFS, OS, AEs, PPD PDL1 expression/clinical response, PPD TMB/clinical response.

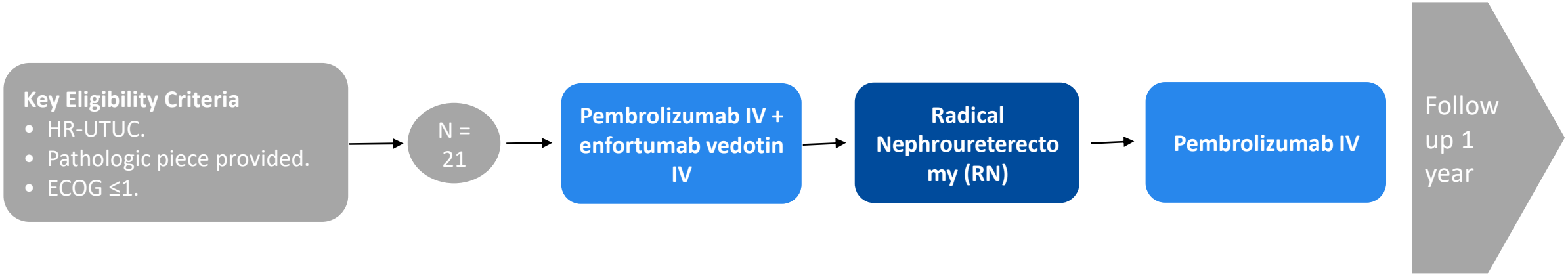
Urothelial Carcinoma – Upper Tract

UCLA Health

NCT05775471

NCT0575471

Phase 2



- **Pembrolizumab**: a mAB directed against PD-1, thereby impairing its interaction with PD-L1 that would prevent an immune response.
- **Enfortumab Vedotin:** antibody drug conjugate that binds to nectin-4 in tumoral cells and stimulates cellular death.

Endpoints:
Primary: ORR, RFS (at/after RN).
Secondary: AEs.

Urothelial Carcinoma – Bladder, Upper Tract

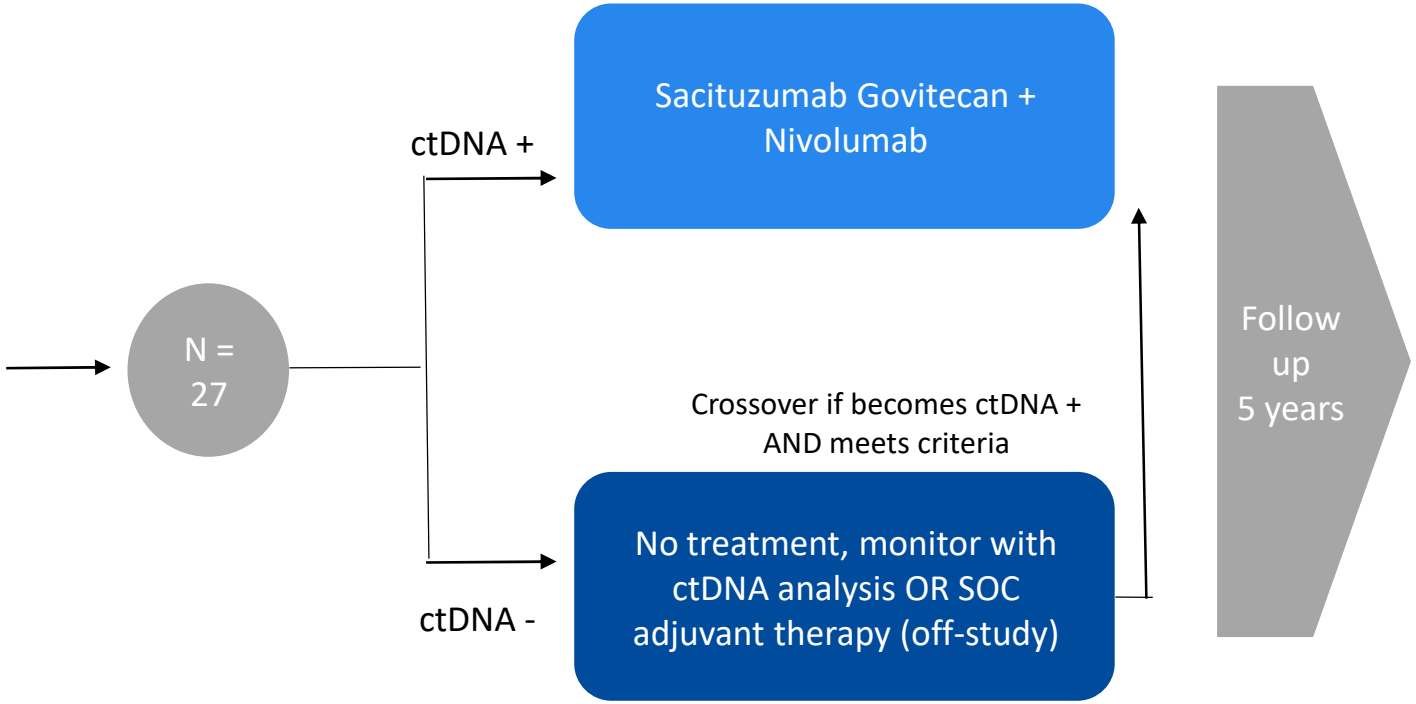
UCI Health

Adjuvant Sacituzumab Govitecan Plus Nivolumab in ctDNA Positive Patients with Muscle-Invasive Urothelial Carcinoma at High-Risk for Recurrence.

Phase 2, Multi-center

Key Eligibility Criteria

- Confirmed UC of the bladder, upper tract or ureter.
- High risk for recurrence based on surgical pathology.
- Previous curative-intent surgery (RC or NU).
- Analysis for ctDNA.



Endpoints:
Primary: ctDNA clearance at 6 months.
Secondary: ctDNA clearance, AEs, DFS, DMFS, OS.

- **Sacituzumab Govitecan:** ADC targeting TROP-2.

Metastatic, 1st line

Bladder Cancer – Metastatic, 1st line

Study Title	Study Design	Other Details
NCT05911295	DV + Pembro vs. Chemotherapy for treatment naïve LA/mUC that is HER2 positive (≥IHC 1+)	• Randomized, phase 3. • No prior systemic therapy. • Evaluation of ADC.

Bladder Cancer – Metastatic, 1st

UCLA Health

NCT05911295

KEYNOTE-D74

Phase 3

Key Eligibility Criteria
- LA/mUC.
- Measurable disease.
- No prior systemic therapy.
- Eligible for cisplatin/carboplatin chemo.
- HER2 xpression (≥1+).
- ECOG ≤2.

→ R (1:1)
N = 700

→ Disitamab vedotin IV Q2W + pembrolizumab 400 mg IV Q6W

→ SOC (gemcitabine 1000 mg/m2 IV D1&8 Q3W + cisplatin 70 mg/m2 IV D1 Q3W OR carboplatin 5 IV D1 Q3W)

→ Follow up 5 years.

- **Pembrolizumab**: a mAB directed against PD-1, thereby impairing its interaction with PD-L1 that would prevent an immune response.
- **DV:** Antibody Drug Conjugate against HER-2, delivering cytotoxic effect to tumoral-expressing cells.

Endpoints:
Primary: PFS, OS.
Secondary: ORR, DOR, DCR, PFS, AEs, QOF.

Metastatic, Salvage

Bladder Cancer – Metastatic, salvage

Study Title	Study Design	Other Details
NCT04579224	Eribulin +/- gemcitabine vs. SOC for mUC refractory to or ineligible for anti PD1/PDL1	• Study redesigned because of change in SOC. • Arm 2 will be Permanently Closed to Accrual
NCT03375307	Use of Olaparib in treating patients with mUC and DNA-repair defects.	• DNA-Repair defects stratification. • Efficacy of Olaparib in the metastatic setting.
NCT05562830	Use of agents +/- pembro in PD1/L! Refractory LA or mUC.	• Single arm. • MUC (Umbrella study,substudy 04A)
NCT04879329	Efficacy and safety of Disitimab Vedotin +/- pembrolizumab in LA/mUC (HER2 +).	• HER2 + UC. • Cohorts A, B, C, and D will enroll simultaneously. Cohort E will begin enrollment after Cohort D participants have completed the DLT evaluation period.
NCT05548296	Efficacy and safety of ACR-368 +/- gemcitabine in platinum-resistant tum	• Phase 1b/2. • Basket trial (endometrial, ovarian, urothelial). • OncoSignature +.
NCT05614739	Safety, efficacy and side effects of LOXO-435	• Sequential assignment. • FGFR3 alterations. • Dose optimization/dose expansion.
NCT05704985	Safety and efficacy of DK210 for LA or metastatic EGFR+ solid tumors.	• Sequential assignment. • EGFR expressing solid tumors. • Il-2/Il-10 coupled agent.

Bladder Cancer – Metastatic, salvage

Keck Medicine of USC

NCT04579224

SWOG S1937

Phase 3

Key Eligibility Criteria
- ≥ 18 years old.
- Previously treated mUC.
- RECIST measurable disease.
- Treated with EV.
- Treated or ineligible for PD1/PDL1 Ab.
- Adequate organ function.
- ECOG ≤ 2.

R (1:1:1)
N = 184

SOC (Sociuzumab govitecan OR docetaxel OR paclitaxel OR gemcitabine)

Eribulin IV 1.4mg/m2 on D1,8 (3 week cycle)

Gemcitabine IV + Eribulin IV: G 1mg/m2 + E 1.4mg/m2 on D1,8 (3 week cycle)

Follow up 3 years.

- **Eribulin**: inhibits microtubule growth.
- **Gemcitabine**: inhibits the transition from the G1-S phase, inhibiting DNA synthesis.

Endpoints:
Primary: OS.
Secondary: PFS, CR, ORR, DOR, DCR

Bladder Cancer – Metastatic, salvage

UC San Diego School of Medicine

NCT03375307

NCT03375307

Phase 2

Key Eligibility Criteria

- Histologically confirmed non-prostate GU cancer.
- Confirmed presence of cancer-associated pathogenic alteration.
- Genic benign or variants of unknown significance.
- Measurable disease.
- Disease progression with at least one platinum-based chemotherapy /ICI.
- Evidence of disease progression.
- ECOG ≤1.

N = 150

Arm I: Cancer-associated DNA-repair gene mutations.

Olaparib orally PO BID on days 1-28 of each cycle.

Arm II: No cancer-associated DNA-repair gene mutations.

Blood sample collection at baseline

Follow up at 4 weeks, every 2 months for 1 year, then every 3 months thereafter.

- **Olaparib:** a poly-ADP-ribose polymerase (PARP) inhibitor that induces lethality in tumor cells with dysfunctional DNA damage repair (DDR) mechanisms.

Endpoints:
Primary: ORR.
Secondary: PFS, AEs, Individual DNA repair defects.

Bladder Cancer – Metastatic, salvage

UC San Diego SCHOOL OF MEDICINE

NCT05562830

KEYMAKER-U04

Phase 1/2

Key Eligibility Criteria
- Confirmed locally advanced/unresectable or mUC of the urinary tract.
- Disease while on or after PD1/PDL1 therapy, alone or in combination with ICIs.
- Disease recurrence while on or after PD1/PDL1 monotherapy.

→ N = 40 → Zilovertamab vedotin 2mg/kg on D1 and D8 of Q3W. →

Follow Up
- 2 years.
- Disease progression or discontinuation criteria met.

- **Zilovertemab Vedotin:** a cleavable, antibody-drug conjugate targeting ROR1. Anti-microtubule payload (cytotoxin mono methyl auristatin E.

Endpoints:
Primary: AEs (Percentage/Discontinuation), ORR.
Secondary: DOR.

Bladder Cancer – Metastatic, salvage

UCI Health

NCT04879329

KEYNOTE-D78

Phase 2, multi-cohort

Key Eligibility Criteria
- Confirmed locally advanced mUC.

Cohort A and B
- Received only 1 or 2 llines
- ≥ 1 measurable lesions
- HER-2 expression

→ Disitimab Vedotin (DV) monotherapy for HER2-positive tumor types

→ DV monotherapy for HER2-low tumor types

Cohort C
- No prior systemic therapy.
- Eligible for platinum chemo.
- HER-2 expression

→ DV + Pembro (non randomized)

Cohort D
- Must have received prior line of platinum chemo, anti PDL1 , EV

→ DV + Pembro (randomized combination) / Randomized monotherapy (Japan only)

Cohort E
- No prior systemic therapy.
- Eligible for chemo.
- HER-2 expression.

→ DV + Pembro (Japan only)

→ Follow up 2 years.

DV: ADC against HER-2, delivering cytotoxic effect to tumoral-expressing cells.

Endpoints:
Primary: cORR, CR, AEs.
Secondary: cORR, DOR, PFS, DCR, OS, AEs.

Bladder Cancer – Metastatic, salvage

UCI Health

NCT05548296

ACR-368-201 (GOG 3082)

Phase 1b/2 (basket trial with ovarian, urothelial and endometrial)

Key Eligibility Criteria
- Locally advanced or mUC.
- Have received platinum regimen.
- Failed or Ineligible for ICIs or EV.
- No life-prolonging therapy is available.
- ≥ 1 measurable lesion with evidence of progression.
- ECOG ≤1

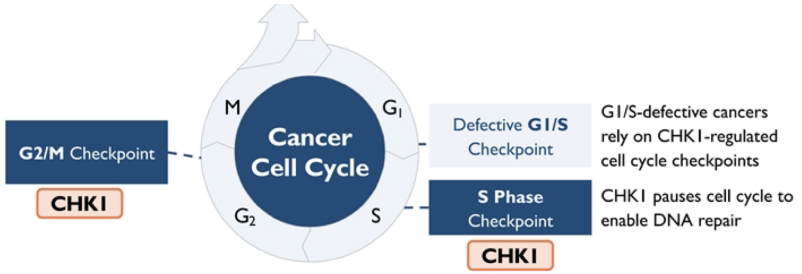
→ N = 390 — OncoSignature →

Positive → ACR-368 as monotherapy

Negative → ACR-368 and ultralow Dose Gemcitabine

→ Follow up, response assessed every 8 weeks to 2 years or death.

- **ACR-368**: Cell cycle checkpoint inhibitor.
- **Gemcitabine:** inhibits the transition from the G1-S phase, inhibiting DNA synthesis.



Endpoints:
Primary: ORR, AEs.
Secondary: AEs, OS, DOR, Pharmacokinetics, DOR, PFS.

Bladder Cancer – Metastatic, salvage

City of Hope

NCT05614739

Keynote-F35

Phase 1a/1b

Phase 1a

Cohort A1 Dose Escalation: All Solid Tumors with an alteration in FGFR3 or its ligands deemed as a clinically or potentially relevant alteration.

Single patient acceleration

MTPI-2 Dose Escalation

Food effects Sub-Study

Moderate Renal Insufficiency Sub-Study

Cohort A2: Dose Optimization
- MUC.
- Known qualifying FDGFr alterations ≥ prior regimen for advanced or metastatic disease
- Prior FGFR inhibitor is allowed but not requires

R (1:1)

DL A

DL B

Phase 1b

RP2D

Cohort B: mUC with FGFR3 alterations

B1: LOXO-435 monotherapy (prior FGFR inhibitor)

B2: LOXO-435 monotherapy (FGFR inhibitor naive)

B3: LOXO-435 + Pembro (FGFR inhibitor naive)

Cohort C: All non-UC Solid Tumors with FGFR3 alterations

C1: LOXO-435 monotherapy (FGFR inhibitor naive)

Endpoints:
Primary: PK, Cmin, DoR, TTR, PFS, DCR, OS, FACT-BI.
Secondary: AUC, Cmin, DoR, TTR, PFS, DCR, FACT-BI, PWB.

- **LOXO-435:** Selective FGFR3 inhibitor.

Bladder Cancer – Metastatic, salvage

City of Hope

NCT05704985

DEKA-1

Phase 1

Key Eligibility Criteria

- Solid tumor known for response on Il-2/Il-10 and/or high expression of EGFR.
- PD at entry.
- Clinical PD with performance decline.
- Failed ≥1 lines of systemic therapy.

Vials

Pre-filled Syringes

Group 1 DK210 (EGFR) 0.025 mg/kg FU 21 days

Group 2 DK210 (EGFR) 0.05 mg/kg FU 21 days

Group 3 DK210 (EGFR) 0.1 mg/kg FU 21 days

Group 4 DK210 (EGFR) 0.2 mg/kg FU 21 days

Group 5 DK210 (EGFR) 0.3 mg/kg FU 21 days

Sequential dose-finding / Tx SC 3x per week.

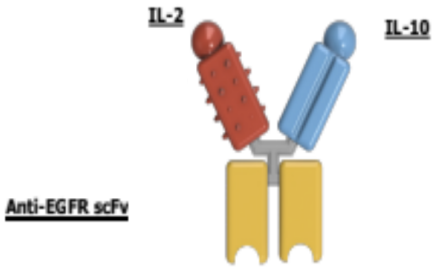
Group 6 DK210 (EGFR) short regimen radiation

Group 7 DK210 (EGFR) + PD-1 blockers

Group 8 DK210 (EGFR) + chemo

Group 9 DK210 (EGFR)

Parallel expansion. Biomarker selection validation.



- **DEKA-210:** Il-10 and Il-2 couples onto a single chain variable.

Endpoints:
Primary: AEs, Dose.
Secondary: ORR, PFS, OS, PK.