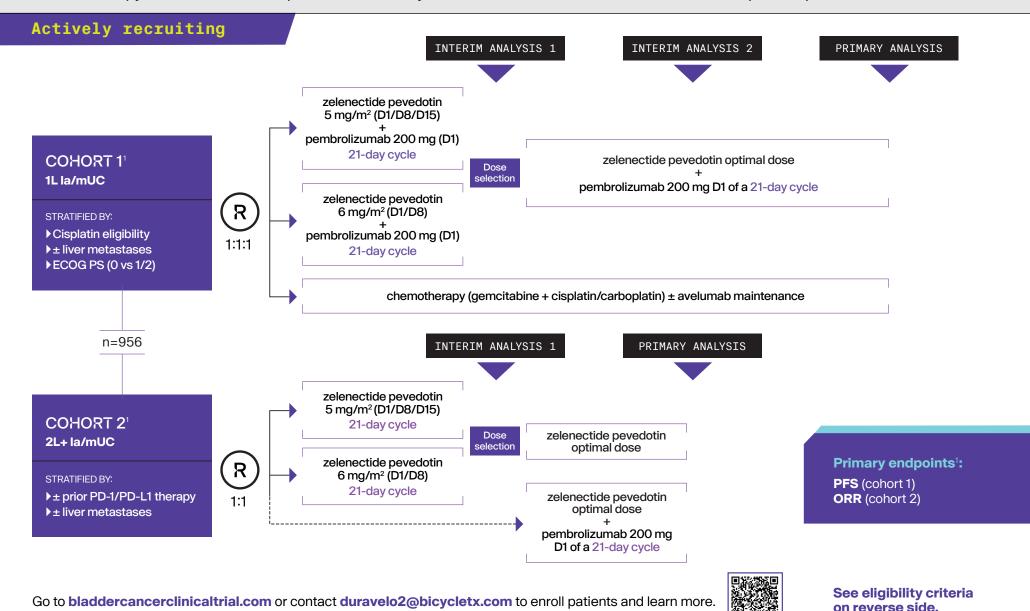


A randomized, open-label, phase 2/3 study of Nectin-4-targeting Bicycle® Drug Conjugate zelenectide pevedotin (BT8009) as monotherapy or in combination in patients with locally advanced or metastatic urothelial carcinoma (la/mUC)



(BT8009-230) NCT06225596

## Are your patients eligible?

Key eligibility criteria

## COHORT 1 (untreated la/mUC)<sup>1</sup>

- Confirmed la/mUC of the renal pelvis, ureter, bladder, or urethra
- ( eGFR ≥30 mL/min
- COG PS ≤2
- No prior systemic treatment for la/mUC<sup>a</sup> and eligible to receive platinum-based chemotherapy
- Prior treatment with a CPI for any other malignancy within the last 12 months
- X Uncontrolled diabetes (HbA1c ≥8%)

## COHORT 2 (previously treated la/mUC)<sup>1</sup>

- Confirmed la/mUC of the renal pelvis, ureter, bladder, or urethra
- Must have received ≥1 prior systemic treatment<sup>b</sup> for la/mUC<sup>c</sup>
- ( eGFR ≥30 mL/min
- ECOG PS ≤1
- Ongoing Grade ≥2 toxicity associated with prior treatment for UC
- × Prior treatment with EV or any other MMAE-based therapy
- Uncontrolled diabetes (HbA1c ≥8%)

The Duravelo-2 study opened in Q1 of 2024. At the most recent data cutoff from Duravelo-1, zelenectide pevedotin demonstrated a tolerable safety profile and preliminary antitumor activity as monotherapy and in combination with pembrolizumab in mUC.<sup>2-5</sup>

Go to bladdercancerclinicaltrial.com or contact duravelo2@bicycletx.com to enroll patients and learn more.



## Product candidates are investigational only and are not approved medicines.

<sup>a</sup>Patients with prior neoadjuvant/adjuvant chemotherapy, MMAE-based therapy, and immune checkpoint inhibitor therapy with recurrence >12 months from completion of therapy are allowed.

blncluding neoadjuvant/adjuvant platinum-based chemotherapy if recurrence occurred <12 months of completing therapy.

°The percentage of patients who had received prior PD-1/PD-L1 inhibitor is capped at 50%1

CPI=checkpoint inhibitor; ECOG PS=Eastern Cooperative Oncology Group performance status; eGFR=estimated glomerular filtration rate; EV=enfortumab vedotin; HbA1c=hemoglobin A1C; la/mUC=locally advanced or metastatic urothelial carcinoma; MMAE=monomethyl auristatin E; mUC=metastatic urothelial carcinoma.

References: 1. Loriot Y, et al. Presented at: 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4; Chicago, IL. Abstract TPS4619. 2. Baldini C, et al. Presented at: 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL. Abstract 498. 3. Bader J, et al. Presented at: 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL. Abstract 3088. 4. Reig Torras O, et al. Presented at: European Society for Medical Oncology (ESMO) Congress 2024; September 13-17, 2024; Barcelona, Spain. Abstract 652P. 5. Giannatempo P, et al. Abstract presented at 2025 Society of Clinical Oncology (ASCO) Annual Meeting; May 30-June 3; Chicago, IL.

