JAVELIN

Bladder Medley (NCT05327530)

Avelumab is not approved for investigational use as described in Groups B, C, and D. Its safety and efficacy in these uses have not been established.
Regulatory approval varies from country to country. Please check your local market authorization label for country-specific information.
Sacituzumab govitecan is not approved for this investigational use. Its safety and efficacy in this use have not been established.
M6223 and NKTR-255 are investigational compounds. Their safety and efficacy have not been established

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

A phase 2, multicenter, randomized, open-label, parallel-arm, umbrella study of avelumab in combination with other antitumor agents as maintenance treatment in patients with locally advanced or metastatic urothelial carcinoma (la/mUC) whose disease did not progress with first-line platinum-containing chemotherapy

ACTIVE, NOT RECRUITING

KEY INCLUSION/EXCLUSION CRITERIA*

- Histologically confirmed, unresectable, la/mUC (stage IIIA/IIIB with N1-N3, or stage IV disease, per AJCC/UICC TNM staging system, 8th edition) at the start of first-line chemotherapy
- No disease progression (per RECIST 1.1) following completion of 4-6 cycles of first-line platinum- containing chemotherapy
- Last dose of first-line chemotherapy received 4-10 weeks prior to randomization in this study
- ECOG PS of 0 or 1
- Must not have received prior immunotherapy (eg, interleukins, interferon alfa, immune checkpoint inhibitors, T-cell co-stimulation modulators), anti-Trop2 antibodies, or any of the investigational drugs used in combination with avelumab

TREATMENT

Patients (N=256) will be randomized into one of the treatment groups below

Group A	**Avelumab** monotherapy 800 mg IV every 2 weeks†
Group B	**Avelumab** 800 mg IV every 2 weeks + **sacituzumab govitecan** 10 mg/kg IV on days 1 and 8 of 21-day treatment cycles†
Group C	**Avelumab** 800 mg IV every 2 weeks + **M6223** 1600 mg IV every 2 weeks†
Group D	**Avelumab** 800 mg IV every 2 weeks + **NKTR-255** 3 µg/kg IV every 4 weeks†

STUDY ENDPOINTS

PRIMARY

- Progression-free survival (PFS)¶
- Treatment-emergent adverse events, treatment-related adverse events, and adverse events of special interest#

SECONDARY

- Overall survival
- Duration of response¶
- Objective response¶
- Pharmacokinetics
- Antidrug antibodies for avelumab, sacituzumab govitecan, M6223, and NKTR-255
- Patient-reported outcomes

Study start date: August 2022

Estimated primary study completion date: January 2025

*These are not the complete inclusion/exclusion criteria. For more information about this clinical research study, please visit www.clinicaltrials.gov/ct2/show/NCT05327530. †Until unacceptable toxicity, withdrawal of consent, or initiation of a new treatment. ¶According to RECIST 1.1 as assessed by investigator. #Per National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.

AJCC, American Joint Committee on Cancer; ECOG, Eastern Cooperative Oncology Group performance status; IV, intravenous; la/mUC, locally advanced or metastatic urothelial carcinoma; RECIST, Response Evaluation Criteria in Solid Tumors; TNM, Tumor Node Metastasis; UICC, Union for International Cancer Control.

This information is current as of April 2025.

This material is intended for healthcare professionals only.

For more information on this clinical trial, scan the QR code.

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