# Avelumab in real-world treatment of urothelial cancer – The AVENUE NIS

**First published:** 23/08/2021

**Last updated:** 30/09/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS42413

**Study ID**

48917

**DARWIN EU® study**

No

**Study countries**

- ☐ Germany
- ☐ Russian Federation
- ☐ Spain
- ☐ Switzerland

**Study description**

This study is a prospective, single-arm, observational real-world study in patients with locally advanced or metastatic urothelial cancer conducted in Germany, Spain, Russia and Switzerland. Patients whose disease did not progress on platinum-based first-line chemotherapy and who subsequently receive Avelumab (As per local label) as maintenance treatment in accordance with terms of marketing authorization will be enrolled. A total of approximately 350 eligible patients with locally advanced or metastatic urothelial cancer with any histology will be enrolled in this multi-center study. Patients will be recruited over a period of 36 months and followed up for 36 months from index date (defined as the first administration date, after AVENUE NIS informed consent signature, of Avelumab maintenance therapy to patients with locally advanced or metastatic urothelial cancer), irrespective of whether they continue or discontinue therapy. There will be a safety follow-up at 28 days post discontinuation.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Merck Healthcare KGaA

Germany

**First published:** 26/02/2024

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**Institution**

# Contact details

**Study institution contact**

Communication Center Merck Healthcare Germany GmbH, an affiliate of Merck KGaA, Darmstadt, Germany

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**Study contact**

service@merckgroup.com

**Primary lead investigator**

Jürgen E. Gschwend

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 21/01/2021

Actual: 21/01/2021

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**Study start date**

Planned: 04/09/2021

Actual: 24/09/2021

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**Date of final study report**

Planned: 30/04/2028

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ARES Trading S.A. Zone Industrielle de l’Ouriettaz, CH-1170 Aubonne, Switzerland

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

This study will evaluate effectiveness and safety of Avelumab (acc. to SmPC or local label) as maintenance therapy administered after completion of 1st line platinum-based chemotherapy in patients with locally advanced or metastatic UCC (not progressed with 1st-line platinum-chemotherapy).

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

International, multi-center, prospective, single-arm, observational real-world/non-interventional study

## Study drug and medical condition

**Medical condition to be studied**

Transitional cell cancer of the renal pelvis and ureter

## Population studied

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Estimated number of subjects**

350

# Study design details

**Outcomes**

- To evaluate overall survival (OS) rate at 12, 24, and 36 months after the index date (baseline visit) in patients receiving Avelumab maintenance therapy
- To assess OS and health-related quality of life (HRQoL) in patients receiving Avelumab maintenance therapy
- To evaluate anti-tumor effectiveness and safety and tolerability of Avelumab maintenance therapy
- To assess progression-free survival (PFS) on Avelumab maintenance therapy and progression-free survival 2 (PFS2) on Avelumab maintenance therapy followed by second-line treatment

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**Data analysis plan**

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied. Continuous variables will be described with the following measures of central tendency and dispersion: the number of patients, missing observations, mean, standard deviation, median, interquartile range, minimum, and maximum. Frequency, percentage, and number of missing observations will be provided for categorical variables. Exact Clopper-Pearson 95% CIs will be included where appropriate. The Kaplan-Meier method will be used for the analysis of time to event objectives. In general, descriptive statistics of quantitative parameters (results and change from baseline) will be provided for observed cases, that is, patients having non-missing assessments at a specific timepoint. Missing data count will be presented.

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No