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.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

First published: 26/02/2024

Last updated: 26/02/2024

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

Study start date

Planned: 04/09/2021

Actual: 24/09/2021

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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