Enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer previously treated with chemotherapy and immunotherapy: a multicenter, non-interventional study in Italy (EVIDENCE)

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Study Ongoing

Administrative details

EU PAS number

EUPAS107848

Study ID

199003

DARWIN EU® study

No

Study countries

Italy

Study description

The purpose of this study is to describe the safety and tolerability of enfortumab vedotin (EV), in a real-world setting, in patients treated according to the EMA/AIFA (Italian Medicines Agency) approved indication. This study will also describe how EV drug-related adverse events impacted course of treatment, characteristics of patients treated with EV in real-world clinical practice, describe real-world treatment patterns of EV and describe real-world effectiveness of EV.

Study status

Ongoing

Research institutions and networks

Institutions

Multiple centres: 15 centres involved in the study

Contact details

Study institution contact

Registration Department Clinical Trial
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Ahmet Hasaligil

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/12/2023

Actual: 29/11/2023

Study start date

Planned: 01/04/2024

Actual: 29/05/2024

Data analysis start date

Planned: 01/07/2026

Actual: 15/12/2024

Date of interim report, if expected

Planned: 30/04/2026

Actual: 07/05/2026

Date of final study report

Planned: 30/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

7465-MA-3500

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

To describe the real-world effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To describe the safety and tolerability of EV, in a real-world setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional primary and secondary data collection

Study drug and medical condition

Medicinal product name

PADCEV

Study drug International non-proprietary name (INN) or common name

ENFORTUMAB VEDOTIN

Anatomical Therapeutic Chemical (ATC) code

(L01FX13) enfortumab vedotin

enfortumab vedotin

Medical condition to be studied

Transitional cell carcinoma

Additional medical condition(s)

Locally advanced or metastatic urothelial cancer

Population studied

Short description of the study population

patients with locally advanced or metastatic urothelial cancer previously treated with chemotherapy and immunotherapy

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

200

Study design details

Outcomes

To describe the safety and tolerability of EV, in a real-world setting, To describe real-world effectiveness of EV based on: o How EV drug-related AEs impacted course of treatment o Characteristics of patients treated with EV in real-world clinical practice o Real-world treatment patterns of EV o Real-world effectiveness of EV.

Data analysis plan

No hypothesis will be tested in this study as it is a descriptive, non-interventional retrospective study.

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

Medical records of patients

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