Real-world use of enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer previously treated with chemotherapy and immunotherapy: a multicenter, retrospective, non-interventional study in France

First published: 24/10/2023

Last updated: 31/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS105591

Study ID

105592

DARWIN EU® study

No

Study countries

France

Study description

In France, there was an early access program for people with severe diseases who do not have any other available treatment options. In an early access program, people access new medicines before they are approved by Health Authorities. Enfortumab vedotin is a treatment for cancer in the bladder lining (urothelial cancer). It was available for use in the early access program in France for adults with locally advanced or metastatic urothelial cancer. Locally advanced means the cancer had spread to tissue close by. Metastatic means the cancer has spread to other parts of the body. People in the program had been previously treated with all available standard therapies. In the program they were treated with enfortumab vedotin according to their clinic’s standard practice. This is also known as real-world use. This study is about collecting information about adults with locally advanced or metastatic urothelial cancer from the early access program. They will have received at least 1 treatment with enfortumab vedotin between 08 Jul 2022 and 31 Dec 2022. The main aim of the study is to learn if enfortumab vedotin extended the lives of people taking part in the program. This aim is also called overall survival, or OS. Information will be collected from the medical charts, beginning just before each person started treatment with enfortumab vedotin (also known as the baseline). This will continue with documented information for up to 12 months of treatment, or if the person died or could not be contacted within the 12 months of treatment.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 50

Contact details

Study institution contact

Registration Department Clinical Trial

clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Kahina Makhloufi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/03/2023

Study start date

Planned: 30/11/2023

Actual: 28/11/2023

Data analysis start date

Planned: 31/05/2024

Actual: 06/05/2024

Date of final study report

Planned: 31/01/2025

Actual: 15/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

Study protocol

7465-CL-3480_Redacted Protocol V2.0.pdf (1.38 MB)

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

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

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

To describe the real-world effectiveness

Data collection methods:

Secondary use of data

Study design:

This study is multicenter, retrospective, non-interventional study conducted in France that does not involve the human person as defined in the French legislation (RNIPH, recherche n’impliquant pas la personne humaine).

Main study objective:

To describe real-world effectiveness of EV based on overall survival (OS)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional secondary data-use study

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

Population studied

Short description of the study population

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

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Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - 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

206

Study design details

Outcomes

To describe real-world effectiveness of EV based on OS.

To describe real-world effectiveness of EV based on:

- Progression free survival

- Time to treatment discontinuation

- Time to next treatment

- Objective response rate

- Disease control rate

- Baseline characteristics of participants who initiated treatment with EV

- Describe real-world treatment patterns of EV

- Safety data related to the use of EV in the real world

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)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Other

Data sources (types), other

Chart review

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