Real-life Enfortumab Vedotin Outcomes as First-line Urothelial Carcinoma Treatment in the Non-interventional Observational and Nationwide French Study

First published: 12/11/2025

Last updated: 28/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000763

Study ID

1000000763

DARWIN EU® study

No

Study countries

France

Study description

In France, an early access program gave people with unresectable or metastatic urothelial cancer access to enfortumab vedotin and pembrolizumab before their use together was approved by the health authority. This study will use the information from this early access program. It will also use information from medical charts in medical centers and health insurance records in France to learn more about people with unresectable or metastatic urothelial cancer who use enfortumab vedotin and pembrolizumab. This study is about collecting information only. The individual's doctor decides on treatment, not the sponsor (Astellas). Researchers will learn about the use of enfortumab vedotin together with pembrolizumab in standard clinical practice in France between January 2020 and December 2027.

Study status

Ongoing

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

IQVIA UK

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Matthiew Trancart

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/03/2025

Study start date
Planned: 30/04/2026

Actual: 12/05/2026

Data analysis start date
Planned: 05/05/2026

Date of interim report, if expected
Planned: 23/09/2026

Date of final study report
Planned: 01/12/2028

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-3559

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)

Data collection methods:

Secondary use of data

Study design:

In Part 1 of the study, baseline data from the French EV+P EAP will be re-used and completed with secondary data collection from patients' charts.
In Part 2 of the study, patient baseline clinical characteristics will be re-used from the previously completed EV+P EAP baseline CRF.

Main study objective:

In Part 1 the main aim is to learn how long people receive treatment with enfortumab vedotin and pembrolizumab. Information about people stopping treatment or starting a new treatment will be collected.
In Part 2 the main aim is to learn if enfortumab vedotin and pembrolizumab can extend the lives of people taking part in the program. Information about people's overall health outcomes will be collected.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

KEYTRUDA

PADCEV

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

PEMBROLIZUMAB

ENFORTUMAB VEDOTIN

Anatomical Therapeutic Chemical (ATC) code

(L01FF02) pembrolizumab

pembrolizumab

(L01FX13) enfortumab vedotin

enfortumab vedotin

Medical condition to be studied

Chemotherapy urothelial toxicity attenuation

Population studied

Short description of the study population

Urothelial cancer is the most common type of bladder cancer. Enfortumab vedotin and pembrolizumab are approved medicines being used together to treat cancer in the bladder lining (urothelial cancer) that is unresectable or metastatic. Unresectable means the cancer cannot be removed by surgery. Metastatic means the cancer has spread to other parts of the body

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Age groups

- Adults (18 to < 65 years)

    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
- Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Frail population

Renal impaired

Estimated number of subjects

500

Study design details

Outcomes

Part 1: Time to permanent discontinuation of EV and P will be defined as the time from the first dose of EV+P (index date) to, whichever occurs first:

● The date of death, or

● The date of initiation of any subsequent therapy, or

● The date of permanent discontinuation of both EV and P

Part 2: To describe OS for EV+P

Data analysis plan

The purpose of this secondary data use study is to leverage data available in the French EV+P EAP and medical charts of these patients to understand the use of EV+P (Part 1), and to leverage data in French national claims databases to understand the long-term effectiveness of EV+P (Part 2).

Methodology (Part 1)

Collected data will be recorded from the EV+P early access program (EAP) baseline CRF and completed with data extracted from medical charts previously recorded during routine clinical visits.
Eligible patients will include: Male or female patient ≥ 18 years of age with unresectable or metastatic urothelial cancer at the time EV+P treatment was initiated. Patient treated with at least 1 dose of EV and P between Q4 2024 and Q1 2025 as part of the French EV+P 1L EAP. Inclusion criteria and data collection are designed to ensure at least 1 year of follow-up for each patient.
Methodology (Part 2)
All patients who participated in the French EV+P 1L EAP will be included. As such, patients in Part 1 represent a subgroup of patients from Part 2. Baseline characteristics at inclusion in the EAP will be documented from the EAP CRF database .
Additional baseline and follow-up information will be extracted from the French medico-administrative database [SNDS].
Sample Size
For Part 1, up to 50 sites will be selected to reach a sample size of at least 500 patients.
For Part 2, the actual number of patients is unknown. Inclusions will be interrupted at the end of the French EV+P EAP, once EV and P are available for this indication through standard reimbursement.
Statistical analyses
The primary and secondary effectiveness endpoints will be analyzed by subgroups where sample sizes allow.

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 source(s)

Other data source

Data source(s), other

Part 1

Data will be re-used from the EAP baseline CRF and extracted from medical charts of patients treated at sites that took part in the French EV+P EAP.

Part 2

Data will be re-used from the EAP baseline CRF and extracted from the SNDS. The SNDS covers the entire French population (65.3 million inhabitants) and contains exhaustive data on all reimbursements for health-related expenses, including medicinal products (through standard reimbursement and compassionate use, such as EAP) and outpatient medical and nursing care prescribed or performed by healthcare professionals, as well as demographic data such as age, sex, area of residence (postcode), vital status and complementary universal health insurance.

In addition, data extracted from medical charts in the subset of patients who participate in Part 1 will be re-used, allowing the use of complementary information in these patients (e.g., dose adjustments extracted from medical charts and long-term OS documented from the SNDS).

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Non-interventional study

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