A Non-interventional Real-World Study on Dose Modifications of Enfortumab Vedotin (EV) in Combination with Pembrolizumab (P) in Previously Untreated Patients with Advanced Urothelial Carcinoma in Germany

First published: 21/02/2025

Last updated: 21/02/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000467

Study ID

1000000467

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This is a real-world study; it is about collecting information only. The individual's doctor decides on treatment, not the sponsor (Astellas). Information about how people with advanced urothelial cancer are treated with enfortumab vedotin and pembrolizumab in clinics in Germany will be collected.

Study status

Planned

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Marie Catherine Thomas

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/09/2024

Study start date
Planned: 17/02/2025

Data analysis start date
Planned: 25/11/2027

Date of interim report, if expected
Planned: 26/11/2026

Date of final study report
Planned: 28/03/2028

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-3558

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)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a single arm, multi-center, non-interventional prospective cohort study which aims to describe the use of Enfortumab Vedotin + Pembrolizumab especially, the dose modification, in previously untreated patients with unresectable or metastatic urothelial cancer.

Main study objective:

The main aim of the study is to learn about any changes in the doses of enfortumab vedotin and/or pembrolizumab people receive. Information about dose changes, temporary pauses, or a complete stop of either treatment will be collected. The study will last about 2 years.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

KEYTRUDA

PADCEV

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

ENFORTUMAB VEDOTIN

PEMBROLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FF02) pembrolizumab

pembrolizumab

(L01FX13) enfortumab vedotin

enfortumab vedotin

Additional medical condition(s)

Metastatic urothelial carcinoma

Population studied

Short description of the study population

This study is for adults in Germany who have cancer in the bladder lining that has spread to tissue close by or to other parts of the body (advanced urothelial cancer). The people's advanced urothelial cancer has not previously been treated.

The people in this study will receive enfortumab vedotin and pembrolizumab as part of their usual treatment for their cancer.

Age groups

Adult and elderly population (≥18 years)

Estimated number of subjects

150

Study design details

Outcomes

Dose modification (dose reduction, temporary interruption, permanent discontinuation) for enfortumab vedotin and/or Pembrolizumab

---

Data analysis plan

In order to describe the frequency of real-world dose modifications in 1L unresectable or metastatic urothelial cancer patients receiving enfortumab vedotin + pembrolizumab, dose modification of enfortumab vedotin and/or pembrolizumab will be analyzed as a composite variable of dose reduction, temporary dose interruption, and permanent discontinuation. The frequency of patients experiencing dose modification will be descriptively analyzed. Cumulative incidence of dose modification will be estimated using survival analysis; death will be considered a competing event.

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)

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

Unknown