An observational, Post-Authorisation Safety Study (PASS) to describe the safety and effectiveness of tabelecleucel in patients with Epstein-Barr Virus positive (EBV+) Post-Transplant Lymphoproliferative Disease (PTLD) in a real-world setting in Europe: EBVOLVE study

First published: 22/07/2024

Last updated: 21/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000113

Study ID

1000000113

DARWIN EU® study

No

Study countries

☐ European Union

Study description

The purpose of this PASS is to collect long-term, real-world safety and effectiveness data of patients treated with tabelecleucel, including paediatric and elderly patients. To date, the safety profile of tabelecleucel among paediatric patients remains consistent with that of the overall population; however, additional data are warranted to characterise further the tabelecleucel safety profile in paediatric patients with EBV+ PTLD following HCT or SOT. In addition, the average age of adult patients with PTLD has increased over the last decade due to improved standard, thus, further characterisation of the benefit- risk profile of tabelecleucel in elderly patients (≥ 65 years old) is needed.

All patients who are scheduled to receive tabelecleucel in the real-world setting will be eligible to participate in the study.

Currently treated in any tabelecleucel clinical study or expanded access program will not be eligible to participate in the study.

The treatment decision is to be made prior to and independent of participation in this observational study, and the patient’s treatment plan will not be affected by the participation in this study.

Patients will receive tabelecleucel dosing based on the approved product information (Summary of Product Characteristics, SmPC) and all decisions regarding the treatment of enrolled patients will be made by the treating physician in accordance with the local best clinical practice.

Study objectives:

Primary:

To describe the safety of tabelecleucel in patients with EBV+ PTLD following HCT or SOT in a real-world setting.

Secondary:

1. To describe the effectiveness of tabelecleucel in patients with EBV+ PTLD following HCT or SOT in a real-world setting.
2. To describe the patient population treated with tabelecleucel for EBV+ PTLD following HCT or SOT in a real-world setting.
3. To describe tabelecleucel treatment patterns, including dosing and schedule, in patients with EBV+ PTLD following HCT or SOT in a real-world setting

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Study status

Ongoing

Research institutions and networks

Institutions

ORACLE LIFE SCIENCES

Pierre Fabre Médicament

Contact details

Study institution contact

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Primary lead investigator

Daan Dierickx

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/07/2023

Actual: 12/07/2023

Study start date
Planned: 31/12/2024

Actual: 14/05/2025

Date of final study report
Planned: 01/01/9999

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pierre Fabre Médicament

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This study is an observational, multicenter, multinational PASS with the primary objective of further characterising the safety profile of tabelecleucel and with secondary objectives including the real-world effectiveness of tabelecleucel in patients with EBV+ PTLD following HCT or SOT.

Main study objective:

Primary objective : To describe the safety of tabelecleucel in patients with EBV+ PTLD following hematopoietic cell transplantation (HCT) or solid organ transplantation (SOT) in a real-world setting.
Secondary objectives:
1. To describe the effectiveness of tabelecleucel in patients with EBV+ PTLD following HCT or SOT in a real-world setting.
2. To describe the patient population treated with tabelecleucel for EBV+ PTLD following HCT or SOT in a real-world setting.
3. To describe tabelecleucel treatment patterns, including dosing and schedule, in patients with EBV+ PTLD following HCT or SOT in a real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

EBVALLO

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

TABELECLEUCEL

Anatomical Therapeutic Chemical (ATC) code

(L01XL09) tabelecleucel

tabelecleucel

Additional medical condition(s)

Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+PTLD)

Population studied

Short description of the study population

adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate

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Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

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)

Special population of interest

Nursing women

Other

Pregnant women

Special population of interest, other

patients with organ impairment

Study design details

Setting

The study will be conducted in the real-world setting in institutions experienced in the treatment of cancer and having the permission for allogeneic cell manipulation.

Countries/Region: The study will be conducted in all European countries where tabelecleucel is commercially available in accordance with the launch sequence for commercialisation, which will depend on country-specific reimbursement timelines. There is no limit to the number of patients to be enrolled in the study.

Study Sites: All physicians who are treating one or more patients with tabelecleucel will

be asked to participate in this study, and patients will be asked for consent.

The PASS population will consist of EBV+ PTLD patients who are prescribed tabelecleucel in the real-world setting in Europe and who consent for the secondary use of existing data collected for the purpose of providing tabelecleucel (available in the HCP portal database). In addition, patients will be asked to consent for additional primary data collection in the PASS eCRF system. These data will be obtained on routine clinical practice visits, not collected in the HCP portal database but required to meet all the study objectives.

Outcomes

Safety, effectiveness, demographics, baseline and clinical characteristics, tabelecleucel treatment information

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Data analysis plan

For all subjects enrolled in the PASS, subject-level data will be available for the purposes of analysis and annual reporting.

Statistical analyses will be fully described in a Statistical Analysis Plan (SAP).
Analyses will be performed on an annual basis.
Analyses will be descriptive in nature, as no hypothesis will be tested. In general, missing data will not be imputed (except for dates) and the data will be analysed according to the complete case approach. The frequency of missing data will be indicated in descriptive tables for all variables.
Summary data will be provided for all variables collected and the data will be reported for the whole population and by subgroups.

Data management

Data sources

Data source(s), other

The PASS database will contain complete study specific data for each patient enrolled in the study and will be based on the PASS eCRF that incorporates: (1) secondary use of data from the Health Care Professionnal portal database which will be automatically transferred, incorporated, and displayed in the PASS eCRF, and (2) primary data collection.

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No