Postauthorization Safety Study Survey to Evaluate the Effectiveness of the Ciltacabtagene Autoleucel HCP Educational Program and the Product Handling Training

First published: 14/03/2024

Last updated: 19/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000047

Study ID

1000000047

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Germany
- ☐ Switzerland

Study description

This is a category 3 PASS study with the objective of measuring the effectiveness of the healthcare professional (HCP) Educational Program, an additional risk minimization measure intended to increase awareness about the risks of cytokine release syndrome (CRS) (including hemophagocytic lymphohistiocytosis) and neurologic toxicity (including immune effector cell associated neurotoxicity syndrome and other neurotoxicities); as well as the potential risk of cell viability due to inappropriate handling or preparation of the product, and the HCP awareness of the need to provide patients of a patient CAR-T Journey Guide with its enclosed Patient Alert Card to improve their understanding of the risks associated with CAR-T therapy and how to better manage them.

Study status

Ongoing

Research institutions and networks

Institutions

Johnson & Johnson

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Imene Haddad RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

Primary lead investigator

Siobhan Murphy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/11/2023

Actual: 12/11/2023

Study start date

Planned: 02/01/2024

Actual: 02/01/2024

Date of final study report

Planned: 14/02/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fully funded by Johnson and Johnson

Study protocol

19Jun2025-Protocol-FD-JNJ-amendement 1.pdf(295.16 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

PCSONCA0014

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

RMP educational materials

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

A survey will be completed independently by CAR-T HCPs to measure the effectiveness of the educational materials relating to safe and effective use of ciltacel. HCPs can include physicians, pharmacists, nurses and ward staff from CAR-T centers certified by the sponsor.

Main study objective:

To measure the effectiveness of the HCP Educational Program, an additional risk minimization measure intended to increase awareness about the risk of CRS and neurologic toxicity; the potential risk of cell viability; and the HCP awareness of the patient CAR-T Journey Guide with its enclosed Patient.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Postauthorization Safety Study healthcare professional Survey

Study drug and medical condition

Name of medicine

CARVYKTI

Anatomical Therapeutic Chemical (ATC) code

(L01XL05) ciltacabtagene autoleucel

ciltacabtagene autoleucel

Population studied

Short description of the study population

HCPs from the CAR-T centers certified by the sponsor for ciltacabtagene autoleucel treatment will be invited to participate in the survey: HCPs involved in the prescription and management (i.e., dispensing or administration) of ciltacabtagene autoleucel treatment. And also HCPs involved in the transport, storage, thawing, preparation, or handling of ciltacabtagene autoleucel.
All participants will be independently recruited through a third-party vendor. Participation in this survey will be completely voluntary. No patients will participate in the survey.

Age groups

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)

Adults (85 years and over)

Estimated number of subjects

220

Study design details

Setting

NA

Comparators

NA

Outcomes

The key messages to be tested by the survey include but are not limited to messages about prescription and management of ciltacabtagene autoleucel. For CRS management, participants will be referred to the CRS management table in the SmPC. Additionally, key messages about transport, storage, thawing, preparation, or handling of ciltacabtagene autoleucel will carry a heavier weight for the results for HCPs involved in these processes (i.e., pharmacists and ward staff).

Data analysis plan

A minimum total score of ≥80% across all survey questions will be considered indicative of satisfactory effectiveness. This threshold represents the ‘vast majority’ of correct responses and is consistent with the threshold in previous surveys of risk minimization measures conducted by the sponsor. Upon

completion of the survey by the required number of sample respondents, responses will be aggregated and tabulated. Summary results for the overall achievement of a satisfactory effectiveness score and 95% Clopper-Pearson (exact) CI will be presented for absolute numbers of respondents and percentages of the total sample. For each question, the proportion of respondents answering it correctly will also be presented.

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

The data source for this survey will be the online questionnaire, an HCP survey.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown