Real-world Evidence Study on Brentuximab Vedotin Retreatment Outcomes of Cutaneous T-cell Lymphoma Patients (Brentuximab-5020)

First published: 24/05/2023

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104805

EU PAS number

EUPAS104804

Study ID

104805

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain

Study description

The main aim of this study is to describe how effective and safe the re-treatment of adults with cutaneous T-cell lymphoma (CTCL) with brentuximab vedotin is. Another aim is to describe treatment patterns of persons with CTCL who have received brentuximab vedotin again. No treatment will be provided during this study. Information already existing in the participants' medical charts will be reviewed and collected.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2021

Study start date

Planned: 31/07/2024

Actual: 10/01/2024

Date of interim report, if expected

Planned: 30/07/2024

Date of final study report

Planned: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The main objective of this study is to describe the safety and effectiveness of Brentuximab Vedotin (BV) retreatment in participants with CTCL.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ADCETRIS

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

BRENTUXIMAB VEDOTIN

Anatomical Therapeutic Chemical (ATC) code

(L01XC12) brentuximab vedotin

brentuximab vedotin

Medical condition to be studied

Cutaneous T-cell lymphoma

Population studied

Age groups

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

50

Study design details

Outcomes

- Objective Response Rate (ORR)
- Progression Free Survival (PFS)
- Time to Next Treatment (TTNT)
- Incidence & Grading of Motor Neuropathy
- Time to Improvement & Resolution of Motor
- Neuropathy Incidence & Grading of Sensory Neuropathy
- Time to Improvement & Resolution of Sensory Neuropathy
- Incidence & Grading of Neutropenia
- Incidence & Grading of Febrile Neutropenia
- Incidence & Grading of Serious Infections,
- Number of Participants With Cutaneous Lymphoma Co-Medications or Strategies Used to Treat CTCL Disease --
- Number of Cycles of BV Administered Time Interval Between BV Administration

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Data analysis plan

The summary tables with measures of central tendency and standard deviation for continuous variables and frequency distributions would be presented as a part of the descriptive analysis. Main results would consist of summary across countries, with subgroup analysis stratified by variables of interest performed based on number of participants in each subgroup. There would be a summarization of participants characteristics, treatment patterns and outcomes. To understand the association between participants' characteristics and study outcomes Univariate and Multivariate regression analyses would be performed. Kaplan-Meier survival analysis with 95% will be presented.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Participants data would be collected from their Medical Charts.

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