C25023: Effectiveness and Safety for Re-treatment with Brentuximab-Vedotin (BV) in Patients with Relapsed/Refractory (R/R) CD30+ malignancies: a retrospective medical chart review study in Spain. The BELIEVE Study.

First published: 07/01/2022

Last updated: 10/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44653

Study ID

44654

DARWIN EU® study

No

Study countries

Spain

Study description

Participants in the study are adults with CD30-positive malignancies which include classical Hodgkin lymphoma (cHL), cutaneous T-cell lymphoma (CTCL): mycosis fungoides (MF) or primarily cutaneous anaplastic large cell lymphoma (pcALCL), or systemic anaplastic large cell lymphoma (sALCL). The main aims of the study are as follows: to learn about the response rates of participants with relapsed or refractory CD30+ malignancies when re-treated with BV, to check for side effects from re-treatment with BV. The study will take place in hospitals in Spain. The study doctors will review each participant's medical record at least 6 months after finishing the last dose of re-treatment with BV. This study is about collecting existing information only, participants will not receive treatment or need to visit a study doctor during this study.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda Trialdisclosures@takeda.com

Study contact

Trialdisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/07/2020

Study start date

Actual: 29/10/2021

Data analysis start date

Planned: 31/07/2022

Actual: 29/10/2021

Date of interim report, if expected

Actual: 07/09/2023

Date of final study report

Planned: 31/01/2023

Actual: 30/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Amendment 1_BELIEVE Study Protocol V 2.0 10SEP2021_SIGNED.pdf(4.5 MB)

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

ClinicalTrials.gov PRS: NCT04998331

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Primary objective of the study is to assess the effectiveness and safety of re-treatment with Brentuximab-Vedotin in participants with Relapsed/Refractory (R/R) cHL/CTCL, MF and pcALCL, sALCL.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Hodgkin's disease

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

35

Study design details

Outcomes

The primary outcomes will assess the overall response rate (ORR) as assessed by investigator based on positron emission tomography/computerized tomography (PET/CT) status, number of participants reporting one or more adverse events (AEs). Secondary outcomes will assess duration of response (DOR) based on PET/CT status, overall survival (OS), percentage of participants with complete response based on PET/CT status, time to clinical response (CR or PR), time to best response, time to treatment failure (TTF).

Data analysis plan

Descriptive statistics will be presented as counts or percentages for discrete variables and as median (interquartile range), mean, standard deviation, or standard error of the mean for quantitative variables. All data will be analyzed for overall sample and for different subgroups: cHL, CTCL and sALCL. Kaplan-Meier curves will be used for time-depending variables as PFS, DOR, TTF and OS.

Documents

Study results

C25023-clinical-study-report-redact.pdf(1.17 MB)

Data management

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 will be collected by hematologist/oncologist from the medical record of participants will be recorded in electronic case report forms (e-CRFs).

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