Brentuximab-5014: Brentuximab Vedotin Administration Registry and Outcomes Study in Polish CTCL Patients (BV-BALTIC study)

First published: 06/10/2020

Last updated: 10/11/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS36934

Study ID

44155

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This is a prospective, multicenter, observational, open-label study. This study is designed to document the management and clinical outcome of brentuximab vedotin in cutaneous T-cell lymphomas (CTCL) Polish patients who are eligible for Drug Program (DP) based on local real-world data in Poland. DP is a reimbursement program authorized by Ministry of Health in this country to grant patients access to highly specialized therapies, example biologics, such as brentuximab vedotin. The study is based on data collection from all patients enrolled for treatment in DP between October 2020 and October 2022. All patients will be enrolled in one Cohort, where patient will receive brentuximab vedotin as per summary of product characteristic (SmPC) and DP. Data collection will be scheduled in line with DP visits at every 6 weeks Visit 1 (Week 0) to Visit 9 (Week 48) for up to 16 cycles. The follow up of 6 months post treatment cessation, will be conducted on patients who completed all 16 cycles of treatment and achieved response/remission. The study is planned to be conducted in Poland. The overall duration of this study is approximately 42 months.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

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Contact details

Study institution contact

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Primary lead investigator

Małgorzata Sokołowska-Wojdyło

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/04/2020

Actual: 09/04/2020

Study start date

Planned: 20/10/2020

Actual: 17/11/2020

Data analysis start date
Planned: 01/08/2024

Date of final study report
Planned: 01/12/2024

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective of the study is to determine objective skin response which lasted 4 months or longer (sORR4) measured by modified severity weighted assessment form (mSWAT) and to measure best overall skin response, (Best overall skin response rate BsORR) measured by mSWAT.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

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

60

Study design details

Outcomes

The primary endpoint is percentage of patients with sORR4 measured by mSWAT, complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD) as best response at any time between initiation and cessation of the treatment, and incidence rate of adverse events and serious adverse events. The secondary endpoint is progression free survival and duration of response.

Data analysis plan

Data will be summarized using standard descriptive statistics. For primary and secondary endpoints percentages will be calculated and presented with 95 percent (%) confidence intervals. For secondary endpoints survival analysis using Kaplan-Meier method will be used. Subgroups will be compared using appropriate statistical tests: Chi-square or Fisher test (for categorical data), Two-sample t-test or U Mann-Whitney test for numeric data.

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

Prospective patient-based data collection

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