

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

**First published:** 06/10/2020

**Last updated:** 10/12/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36934

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### Study ID

44155

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### DARWIN EU® study

No

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### Study countries

 Poland

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### 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.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Takeda**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Szymon Drygala

## Contact details

### Study institution contact

Szymon Drygała [trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

Study contact

[trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

### 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

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### Study start date

Planned: 20/10/2020

Actual: 17/11/2020

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### **Data analysis start date**

Actual: 15/08/2025

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### **Date of final study report**

Planned: 31/10/2025

Actual: 19/11/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[Brentuximab-5014-clinical-study-protocol-redact \(1\).pdf](#) (1.03 MB)

[Brentuximab-5014-clinical-study-protocol-redact.pdf](#) (4.44 MB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

Prospective, multicenter, observational, open-label study designed

**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

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**Anatomical Therapeutic Chemical (ATC) code**

(L01FX05) brentuximab vedotin

brentuximab vedotin

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**Medical condition to be studied**

Cutaneous T-cell lymphoma

## Population studied

**Short description of the study population**

Study subjects were patients with mycosis fungoides or primary cutaneous anaplastic large cell,

with the presence of the CD30+ antigen in the lymphoma tissue. Eligible patients were male or

female subjects, aged  $\geq 18$  years, included in the CTCL Drug Program between October 2020 and

April 2024 who received treatment according to the Adcetris (brentuximab vedotin) SmPC. There

was no predefined sample size, and all data entered in the study database were considered for the analysis.

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**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)
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### **Estimated number of subjects**

60

## Study design details

### **Setting**

The study is planned to be conducted in approx. 10 sites in Poland. The sites in BV-BALTIC study will be hospitals and clinics administrating BV in the frames of CTCL Drug Program.

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### **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.

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### **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.

## Documents

## Study results

[Brentuximab-5014-clinical-study-report-redact.pdf](#) (1.19 MB)

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## 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](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No