Non-interventional, post-authorization efficacy study to assess the consistency of Breyanzi product quality and clinical outcomes in patients treated for relapsed/refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, and follicular lymphoma Grade 3B after 2 or more lines of systemic therapy in the post-marketing setting (CA082-1105)

First published: 20/03/2023

Last updated: 25/06/2025

Study Planned

Administrative details

EU PAS number

EUPAS103852

Study ID

103853

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Croatia
- Czechia
- Denmark
- Finland
- France
- Germany
- Greece
- Italy
- Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden
- Switzerland
- United Kingdom

Study description

The aim of this study is to further assess the consistency of Breyanzi product quality measured at the time of release and clinical outcomes in patients treated in the post-marketing setting for relapsed/refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, and follicular lymphoma Grade 3B after 2 or more lines of systemic therapy. These data will contribute to the evaluation of the need for a revision of the finished product

specifications.

Study status

Planned

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

EBMT

Contact details

Study institution contact

Montserrat Miret ctt.group@bms.com

Study contact

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Primary lead investigator

Montserrat Miret

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/08/2022

Study start date
Planned: 18/03/2023

Data analysis start date
Planned: 18/03/2023

Date of interim report, if expected
Planned: 31/12/2024

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Study protocol

ca0821105-nir-protamend-v2-redacted.pdf (373.33 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/PSP/S/0098.1

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The aim of this study is to further assess the consistency of Breyanzi product quality measured at the time of release and clinical outcomes in patients treated in the post-marketing setting for R/R DLBCL, PMBCL, and FL3B after 2 or more lines of systemic therapy. These data will contribute to the evaluation of the need for a revision of the finished product specifications.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BREYANZI

Medical condition to be studied

Follicular lymphoma

Additional medical condition(s)

relapsed/refractory diffuse large B-cell lymphoma,primary mediastinal B-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

30

Study design details

Outcomes

Overall response rate (ORR) Complete response rate (CRR) Duration of response (DoR) Progression-free survival (PFS) Overall survival (OS) Presence and severity of cytokine release syndrome (CRS) post Breyanzi infusion Presence and severity of neurotoxicity post-Breyanzi infusion

Data analysis plan

The quality attributes of the infused products and corresponding clinical outcomes in patients treated with Breyanzi will be presented using a line listing including both product and patient variables. Additionally, summary tables and graphs will be presented. The Quantile Range method will be adopted to identify any outliers or errors in the data. No imputations will be performed for missing values. In order to describe batch analysis quality data, graphs such as scatter plots and run charts will be used to perform qualitative, visual assessment. The absence of shifts and trends in the graphs will be sufficient to ascertain consistency in product quality. No formal hypothesis testing is planned.

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 source(s), other

CIBMTR United States, EBMT

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