# 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**

ctt.group@bms.com

**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

## 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