CA082-1105

Bristol Myers Squibb™

POST-AUTHORIZATION EFFICACY STUDY INFORMATION

Title	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
Protocol version identifier	CA082-1105
Report Date	14-Oct-2022
Date of last version of protocol	26-May-2022
EU PAS Register number	Not available
Active substance	Lisocabtagene maraleucel (liso-cel; JCAR017/BMS-986387) Anti-cancer, immuno-oncology L01XX (Other antineoplastic agents)
Medicinal product	BREYANZI®
Product reference	EU/1/22/1631/001
Procedure number	EMEA/H/C/004731/0000
Marketing authorization holder(s)	Bristol-Myers Squibb Pharma EEIG
Research question and objectives	Research Question 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.

	Primary Objective • To describe batch analysis quality data • To describe corresponding clinical outcomes for each patient Secondary Objective • To describe progression-free survival and overall survival for each patient
Country(ies) of study	European countries
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MARKETING AUTHORIZATION HOLDER

Marketing authorization holder (MAH)	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland
MAH contact person	[redacted] Regulatory Affairs Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge, UB8 1DH, United Kingdom Telephone: [redacted] Email: [redacted]

Bristol-Myers Squibb Company

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2 LIST OF ABBREVIATIONS

Term	Definition
3L+	Third line or later
AE	Adverse event
BMS	Bristol Myers Squibb
CAR	Chimeric antigen receptor
CD	Cluster of differentiation
CR	Complete response
CRO	Contract Research Organization
CRR	Complete response rate
CRS	Cytokine release syndrome
CT	Computerized tomography
DLBCL	Diffuse large B-cell lymphoma
DOR	Duration of response
EBMT	European Society for Blood and Marrow Transplantation
EMA	European Medicines Agency
EU	European Union
EU PAS Register	European Union electronic Register of Post-Authorisation Studies
FL3B	Follicular lymphoma Grade 3B
MAH	Marketing Authorization Holder
ORR	Overall response rate
OS	Overall survival
PAES	Post-authorization efficacy study
PASS	Post-authorization safety study
PET	Positron emission tomography
PFS	Progression-free survival
PMBCL	Primary mediastinal B-cell lymphoma
PR	Partial response
[redacted]	
Q1	Quarter 1
Q3	Quarter 3
Q4	Quarter 4
R/R	Relapsed/refractory
[redacted]	

3 RESPONSIBLE PARTIES

This non-interventional post-authorization efficacy study (PAES) is sponsored by Celgene, a Bristol Myers Squibb (BMS) company, and represents a condition (Annex IID to the European Union [EU] Product Information; BMS 2022)[1] of the European Medicines Agency (EMA) marketing authorization for Breyanzi in relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), primary mediastinal B cell lymphoma (PMBCL), and follicular lymphoma Grade 3B (FL3B) after 2 or more lines of systemic therapy, hereafter referred to as EU third line or later (3L+) approved indication.

This study will be based on data retrieved from the BMS internal database and on secondary use of data that are collected from existing independent registries such as, but not limited to, the European Society for Blood and Marrow Transplantation (EBMT) registry. Treatment centers that have an agreement with the registry holder(s) will contribute, reporting data to the registry(ies). The registry holder(s) will be responsible for the quality of the data held within the registry database(s). At regular intervals, data will be transferred from the registry database(s) to the Marketing Authorization Holder (MAH) in line with the signed informed consent forms.

BMS is responsible for the design and oversight of the analysis described in this protocol.

The responsibilities of the different parties are listed in study-specific documents.

BMS Study Director

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4 ABSTRACT

4.1 Title

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

Version: 2.0

Date: 14-Oct-2022

Main author: [redacted] Epidemiology/Hematology, Worldwide Patient Safety, Bristol Myers Squibb

4.2 Rationale and Background

Breyanzi is a cluster of differentiation (CD)19-directed genetically modified autologous cell-based product consisting of CD8+ and CD4+ T cells, that have been [redacted] transduced ex vivo using a replication incompetent lentiviral vector. On 04-Apr-2022, the European Commission granted Marketing Authorization for Breyanzi in the European Union (EU) for the treatment of relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), and follicular lymphoma Grade 3B (FL3B) after 2 or more lines of systemic therapy, referred to as EU third line or later (3L+) approved indication.

This non-interventional post-authorization efficacy study represents a condition (Annex IID to the EU Product Information; BMS 2022)[1] of the European Medicines Agency (EMA) marketing authorization for Breyanzi and is captured in the EU Risk Management Plan for Breyanzi.

The purpose of this study is to further assess the consistency of Breyanzi product quality [redacted] and clinical outcomes in patients treated with a Breyanzi [redacted]

This study will be a registry-based study including patients from existing independent registries run by the registry holder(s). Batch quality data retrieved from the Bristol Myers Squibb (BMS) internal batch quality database will be provided along with corresponding safety and effectiveness data collected by the registry holder(s).

4.3 Research Question and Objectives

Research Question

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.

Primary Objectives

The primary objectives of this study are:

- To describe batch analysis quality data
- To describe corresponding clinical outcomes for each patient

Secondary Objective

- To describe progression-free survival and overall survival for each patient

4.4 Study Design

This study is designed as a non-interventional single cohort study of patients treated in the post-marketing setting for the EU 3L+ approved indication. This study will use product quality

data [redacted] and will make secondary use of safety and effectiveness outcomes collected by the registry holder(s).

4.5 Population

The study population will consist of [redacted] eligible patients who are treated with Breyanzi for the EU 3L+ approved indication in the post-marketing setting and who are documented within existing independent registries such as, but not limited to, the European Society for Blood and Marrow Transplantation (EBMT) registry. The [redacted] eligible patients who contribute with patient-level data will be selected. One patient will correspond to one Breyanzi lot (consisting of both CD4+ and CD8+ drug product components).

Data from eligible patients treated with Breyanzi will be collected until death, loss to follow-up, withdrawal of consent, or end of the study data collection period, whichever occurs first.

4.6 Variables

The variables needed for this non-interventional study include drug product quality attributes [redacted] and outcome variables generated as part of routine medical practice [redacted].

[redacted]

Variables obtained from the EBMT registry database include:

- Baseline patient and disease characteristics, prior therapies
- Breyanzi infusion information (eg, infusion date, actual dose infused)
- Variables required to derive effectiveness outcomes (overall response rate, complete response rate, duration of response, progression-free survival, overall survival) including best overall response and date of response assessment, date of disease relapse or progression, date of subsequent therapy for the primary disease post Breyanzi infusion, survival status and date of death or last contact with patient, primary cause of death
- Safety outcomes including cytokine release syndrome and neurotoxicity

[redacted]

4.7 Data Sources

Data for this non-interventional study will be retrieved from two types of sources: 1) the BMS internal batch quality database and 2) existing independent registries such as, but not limited to, the EBMT registry database (secondary use of data). Treatment centers across Europe that have an agreement with the registry holder(s) will contribute, reporting data on patients receiving Breyanzi to the registry(ies). Data from the two types of sources will be linked via a set of unique identifiers and will be integrated into one internal data system built and managed by the Sponsor.

[redacted]

4.9 Study Analysis

The quality attributes of the delivered products and corresponding clinical outcomes in infused patients will be presented [redacted]

4.10 Milestones

Data collection is planned to begin in Quarter 1 (Q1) 2023, which corresponds to the date from which data extraction starts, and will extend to Quarter 3 2026. An interim report of the results will be submitted to EMA [redacted] approximately 15 lots of Breyanzi [redacted]. A final study report based on a minimum of 30 lots of Breyanzi is planned to be submitted to EMA by 31-Dec-2026.

5 AMENDMENTS AND UPDATES

None

6 MILESTONES

Table 6-1: Study Milestones

Milestone	Planned Date
Registration in the EU PAS Register	To be confirmed
Start of data collection	Q1 2023
End of data collection	[redacted]
Interim report	[redacted]
Final report of study results	31-Dec-2026

EU PAS Register, European Union electronic Register of Post-Authorisation Studies; Q1, Quarter 1; [redacted]

7 RATIONALE AND BACKGROUND

Breyanzi is a cluster of differentiation (CD)19-directed genetically modified autologous cell-based product consisting of purified CD8+ and CD4+ T cells, in a defined composition, that have been [redacted] transduced ex vivo using a replication incompetent lentiviral vector. CD8+ and CD4+ drug product components play synergistic roles in mediating antitumor activity.

Breyanzi CD8+ and CD4+ drug product components [redacted] enable controlled dose of both components. All CD8+ and CD4+ drug product lots are subjected to release testing at the time of manufacture. Quality parameters associated with release specifications include purity, safety, potency, identity and strength.

On 04-Apr-2022, the European Commission granted Marketing Authorization for Breyanzi in the EU for the treatment of R/R DLBCL, PMBCL, and FL3B after 2 or more lines of systemic therapy, hereafter referred to as EU 3L+ approved indication.

[redacted] As a result, further assessment of the consistency of Breyanzi product quality and clinical outcomes was requested by the EMA as a condition of marketing authorization (Annex IID to the EU Product Information; BMS 2022).[1] Annex IID states:

"In order to further assess the consistency of product quality and clinical outcomes, the MAH shall submit batch analysis and corresponding clinical safety and effectiveness data from a minimum of thirty (30) lots of Breyanzi finished product used to treat patients included in a non-interventional study based on secondary use of data from existing registries, according to an agreed protocol. Based on these data the MAH should also provide an evaluation on the need for a revision of the

finished product specifications. Interim reports should be provided after approximately 15 lots and any significant out of trend results should be reported immediately."

Accordingly, this study will assess the consistency of Breyanzi product quality measured at the time of release and clinical outcomes in patients treated with a Breyanzi conforming product in the post-marketing setting for the EU 3L+ approved indication. A [redacted]

8 RESEARCH QUESTION AND OBJECTIVES

8.1 Research Question

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.

8.2 Research Objectives

8.2.1 Primary Objectives

- To describe batch analysis quality data
- To describe corresponding clinical outcomes for each patient.

8.2.2 Secondary Objectives

- To describe progression-free survival (PFS) and overall survival (OS) for each patient.

8.2.3 Exploratory Objectives

Not applicable.

9 RESEARCH METHODS

9.1 Study Design

This study is designed as a non-interventional single cohort study with secondary use of data. This study will obtain data on patients treated in the post-marketing setting for the EU 3L+ approved indication and included in existing independent registries. Batch quality data retrieved from the BMS internal batch quality database will be provided along with corresponding safety and effectiveness outcomes collected by the registry holder(s).

9.1.1 Primary Endpoints

The primary endpoints will be:

- Effectiveness endpoints of overall response rate (ORR), complete response rate (CRR), and duration of response (DOR).
- Presence and severity of selected adverse events (AEs) reported post-Breyanzi infusion:

- Cytokine release syndrome (CRS)
- Neurotoxicity

Effectiveness endpoints are defined as follows:

- **ORR:** ORR is the proportion of patients with a best overall response of complete response (CR) or partial response (PR), where best overall response is defined as the best disease response recorded from Breyanzi infusion until disease relapse or progression or start of new anti-cancer therapy, whichever happens first. If best response is collected by both computerized tomography (CT) and positron emission tomography (PET) methods, best response per PET overrules best response per CT.
- **CRR:** CRR is the proportion of patients with a best overall response of CR, where best overall response is defined as the best disease response recorded from Breyanzi infusion until disease relapse or progression or start of new anti-cancer therapy, whichever happens first. If best response is collected by both CT and PET methods, best response per PET overrules best response per CT
- **DOR**: DOR is defined as the time from the date of first documented disease response (CR or PR) to the date of first documented progression or first documented relapse, or to date of death due to primary disease, whichever happens first. Patients who are alive and have not experienced disease progression, relapse or death due to primary disease before last contact date will be censored at that time, but no censoring will be done for additional treatment.

9.1.2 Secondary Endpoints

To describe PFS and OS for each patient. These effectiveness endpoints are defined as follows:

- **PFS:** PFS is defined as the time from the date of first Breyanzi infusion to the date of event defined as the first documented relapse or progression or death due to any cause, whatever happens first. Patients who did not reach such events before the last contact date will be censored at that time, but no censoring will be done for additional treatment.
- **OS:** OS is defined as the time from the date of first infusion to the date of death due to any cause. All patients will be followed for survival information, regardless of whether they receive additional treatment post-infusion. Patients who are alive at last contact date will be censored at that time, but no censoring will be done for additional treatment.

9.1.3 Exploratory Endpoints

Not applicable.

9.2 Setting

The study population will include patients who are treated with Breyanzi for the EU 3L+ approved indication at contributing registry centers, and who agree to have their data entered into the registry. All patients included in this CA082-1105 PAES will also be part of the JCAR017-BCM-005 post-authorization safety study (PASS) and this CA082-1105 study will make use of data collected as part of the JCAR017-BCM-005 PASS. No additional data will be collected from the registry(ies) for the purposes of this PAES.

The EBMT registry uses electronic case report forms onto which data may be entered directly by the treating centers. All patients included in the EBMT registry are treated by their physicians

according to real-world clinical practice. Physicians are trained to identify and approach patients treated with Breyanzi in order to obtain patient consent for their data to be reported to the EBMT registry and shared with third parties.

9.2.1 Study Population

The study population will consist of at least [redacted] eligible patients who are treated with Breyanzi for the EU 3L+ approved indication in the post-marketing setting and who are documented within existing independent registries such as, but not limited to, the EBMT registry. The [redacted] eligible patients who contribute with patient-level data will be selected. One patient will correspond to one Breyanzi lot (consisting of both CD4+ and CD8+ drug product components).

The study is expected to require up to 12 months to include the planned number of patients. Patients will be followed until death, loss to follow-up, withdrawal of consent, or end of the study data collection period, whichever occurs first. Patients will be followed for up to 3 years as part of this study.

9.2.2 Inclusion Criteria

Patients who meet all the following inclusion criteria will be eligible:

- Treatment with Breyanzi for the EU 3L+ approved indication in the post-marketing setting.
- Signed informed consent to have data reported to the registry and shared with the MAH.

9.2.3 Exclusion Criteria

Not applicable.

9.3 Variables

The variables needed for this non-interventional study include drug product quality attributes generated at BMS, and outcome variables generated as part of routine medical practice or local regulations and obtained from the registry(ies).

9.3.1 Outcomes/Endpoint Variables

Variables required to derive effectiveness (ORR, CRR, DOR, PFS, OS) outcomes include:

- Best overall response and date of response assessment, date of disease relapse or progression, date of subsequent therapy for the primary disease post Breyanzi infusion, survival status and date of death or last contact with patient, primary cause of death

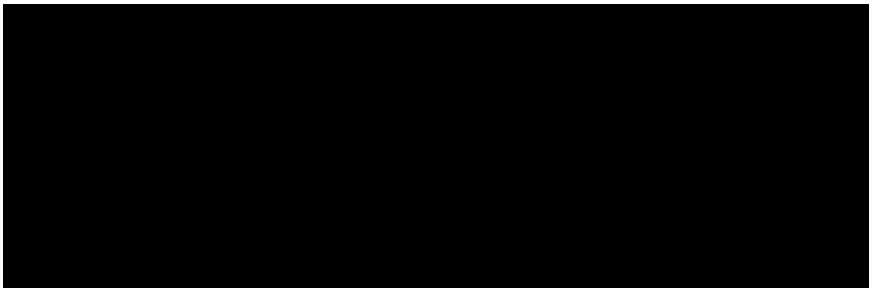
Safety variables include:

- CRS (grade, date of onset and resolution status)
- Neurotoxicity (type of symptom if available, grade, date of onset and resolution status)

9.3.2 Exposure/Independent Variables of Interest

Product quality attributes for both CD4+ and CD8+ drug product components will consist of:

[redacted]



Exposure to Breyanzi will be described using:

- Infusion date
- Actual dose infused

Additionally, the following demographic variables and disease characteristics will be collected for description of the study population:

- Demographics such as:
  - Age
  - Gender
  - Height
  - Weight
- Disease characteristics such as:
  - Primary disease and disease classification (eg, DLBCL, FL3B, PMBCL); date of initial diagnosis
  - Double/triple hit, cytogenetics
  - Prior therapies (number of prior therapy lines and name of prior therapies)
  - Disease status (eg, relapsed or refractory)
- Patient clinical and functional condition:
  - Comorbid conditions
  - Prognostic score (eg, high-risk international prognostic index)
  - Karnofsky performance score
  - Eastern Cooperative Oncology Group performance score

Patients are registered into the EBMT registry from 2 weeks prior to the Breyanzi infusion to any time afterwards. Baseline data are retrospectively reported by data managers after the administration of Breyanzi and are collected only once. All information, including any medical history and measurements done prior to the administration of Breyanzi, becomes available in the registry as baseline data.

No subgroup or multivariable analysis will be performed in the context of this study. Therefore, no subgroup or independent variables are specified here.

9.3.3 Other Co-variates/Control Variables

Not applicable.

9.4 Data Sources

Data for this non-interventional study will be retrieved from two types of sources: 1) the BMS internal batch quality database and 2) existing independent registries such as, but not limited to, the EBMT registry (secondary use of data). Treatment centers across Europe that have an agreement with the registry holder(s) will contribute, reporting data on patients receiving Breyanzi to the registry(ies).

The databases and software used by the EBMT meet the internationally recognized ethical and scientific quality requirements for designing, conducting, recording and reporting studies involving human subjects.

[redacted]

The data will be integrated into one internal data system built and managed by BMS.

9.5 Study Size

The targeted study population is a minimum of [redacted] patients, in line with the Annex IID Condition. [redacted]

9.6 Data Management

This study will make use of registry data collected as part of PASS JCAR017-BCM-005. As the safety and effectiveness data received for this study are secondary, data management activities will be the responsibility of the registry holder(s).

For data obtained from the EBMT registry, sites need to be registered to the EBMT registry system. This registration generates a unique EBMT center identification code and includes trainings on the data collection system. Sites initiate patient reporting through the generation of an EBMT unique identification code, which is unique to every patient. The therapy indication form will identify that the patient is a recipient of Breyanzi and trigger a series of forms appropriate for the specific indication that will be under that unique identification code.

[redacted]

[redacted]

9.7.1 Primary Objectives

Baseline demographic and disease characteristics, quality attributes and clinical outcomes (see Section 9.3) will be presented using descriptive statistics. Summaries and boxplots of quality attributes by clinical outcome (ORR, CRR, CRS, neurotoxicity) will be presented to perform a qualitative visual assessment. For a time-to-event clinical variable such as DOR, Kaplan-Meier plots and associated summary statistics will be presented by quantiles of the quality attributes. The absence of shifts and trends in the graphs will be sufficient to ascertain consistency in product quality.

9.7.2 Secondary Objectives

For PFS and OS, Kaplan-Meier plots and associated summary statistics will be presented by quantiles of the quality attributes. The absence of shifts and trends in the graphs will be sufficient to ascertain consistency in product quality.

9.7.3 Exploratory Objectives

Not applicable.

[redacted]

9.8.1 Database Retention and Archiving of Study Documents

Participating treatment centers must retain medical records for the maximum period required by applicable regulations and guidelines, or institution procedures, independent from the study.

In order to ensure the fulfilment of its pharmacovigilance obligations in relation to the study, the MAH will ensure that the analytical dataset and statistical programs used for generating the data included in the final study report are kept in electronic format and are available for auditing and inspection.

The location of the BMS internal database combining batch quality data and clinical outcomes and supporting documentation will be outlined in the final observational study report.

9.8.2 Registration of Study on Public Website

This study will be registered on the EU electronic Register of Post-Authorisation Studies.

9.9 Limitations of the Research Methods

As this study is based upon secondary use of data, sporadic missing data are inevitable, because certain variables may not have been routinely recorded in the patient medical charts. Furthermore, data may also be missing due to gaps in the follow-up (as routine scheduled visits cannot be mandated in a non-interventional study), and loss to follow-up. [redacted]

In the EBMT registry, data are recorded at baseline, 100 days, 6 months, and then yearly. Thus, owing to center-specific different levels of compliance, a high variability in the recording of assessment dates is to be expected.

To minimize selection bias, sites will be requested to ask every patient treated with Breyanzi to share data with the registry. Nevertheless, not all patients will consent to have their data sent to the registry, possibly resulting in a biased sample of patients.

A high rate of attrition (particularly if mortality is not captured well) could bias the results.

9.10 Other Aspects

Not applicable.

9.10.1 Strengths of Research Methods

This study uses clinical data that reflect current practice in Europe. The EBMT has been qualified as a suitable platform for the collection of data concerning CAR T-cell therapy (EMA 2019).[2] The aim of the EBMT registry is to collect good quality clinical data, which are mainly used for research purposes, and are collected regardless of the conduct of this study and without any involvement of the MAH. It is the largest registry collecting data from cellular therapy patients from European countries. The use of this registry ensures appropriate safety and effectiveness evaluation as the core data elements are predefined according to harmonized cellular therapy definitions (EMA 2018).[3]

The unique lot identification number allows easy linkage of the two data sources.

10 PROTECTION OF HUMAN SUBJECTS

10.1 Ethics Committee Review and Informed Consent

10.1.1 Ethics Committee Review

In accordance with local regulations, this study will complete all required ethical review requirements.

Given that this is a non-interventional study, it does not give rise to additional risks for the safety of the patients.

10.1.2 Informed Consent

Registry data will only be part of the PAES if the patients (and parental/legal representative, when applicable) have given their voluntary informed consent to allow data to be provided to the registry holder and to be shared with competent health authorities, MAH, and other parties in line with the signed informed consent forms.

The informed consent forms used to consent patients will be based upon the registry holders' informed consent form templates, updated in line with the treatment center's standard practices/regulations to fulfill data protection and/or national requirements for informed consent.

In addition, the BMS CAR T patient privacy notice and/or consent forms, developed in accordance with applicable data privacy legislation, that are being provided and collected (if applicable) by BMS prior to a patient's treatment with the cell therapy product, authorize the use of the collected patient data in the BMS internal database for the purpose of this study and any associated post-marketing regulatory or legal requirement.

10.2 Confidentiality of Study Data

The confidentiality of records that could identify patients within the database must be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

11 MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study is not designed to identify new safety events associated with Breyanzi treatment. All patients included in this study are also part of the JCAR017-BCM-005 PASS, which describes the management and reporting of safety information. Selected AEs associated with Breyanzi treatment will be reported by healthcare professionals using EBMT standard registry forms. In addition, healthcare professionals should follow local requirements for spontaneous reporting of adverse drug reactions.

12 PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

BMS is [redacted] to submit to EMA an interim report [redacted] and the final study report by 31-Dec-2026.

13 REFERENCES

1 Bristol-Myers Squibb Pharma EEIG. Breyanzi EU Product Information. 08-Apr-2022. Available from: https://www.ema.europa.eu/en/documents/product-information/breyanzi-epar-product-information_en.pdf

2 EMA Committee for Medicinal Products for Human Use. Qualification opinion on Cellular therapy module of the European Society for Blood & Marrow Transplantation (EBMT) Registry. 28-Feb-2019. Available from: https://www.ebmt.org/sites/default/files/2019-03/EMA%20qualification%20opinion%20on%20Cellular%20therapy%20module%20of%20the%20EBMT%20Registry-28022019.pdf. Accessed 27-Apr-2022.

3 EMA Pharmacovigilance and Epidemiology Department. Report on CAR T-cell therapy Registries Workshop 9-Feb-2018. 15-May-2018. Available from: https://www.ema.europa.eu/en/documents/report/report-car-t-cell-therapy-registries-workshop_en.pdf. Accessed 27-Apr-2022.