Breyanzi

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB / EMA/VR/0000360140	Outcome: This was an application for a group of variations.	31/07/2026			

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	Q.I.b.3 Change to an in-house reference standard/preparation for a biological active substance - Q.I.b.3.e) Other change to the qualification protocol for the prepartation/replacement of an in-house reference standard or preparation - Accepted Q.I.b.3 Change to an in-house reference standard/preparation for a biological active substance - Q.I.b.3.b) Replacement of an in-house reference standard/preparation not covered by an approved qualification protocol, where comparability test results using current and proposed reference standard/preparation material are available - Accepted				
Variation type II / EMA/VR/0000327431	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Submission of the final report from study CA082-1105 listed as a Specific Obligation in the Annex II of the Product Information. This is a non-interventional study submitted to summarize the consistency of Breyanzi product batch quality data measured at the time of release and clinical outcomes in patients treated with Breyanzi in the post-	23/07/2026		Annex II and Labelling	With the submission and assessment of study CA082-1105 listed as a Specific Obligation in the Annex II the MAH has fulfilled their obligation and therefore it has been deleted from Annex II.

	marketing setting for R/R LBCL within the approved indications and dose range per the EU PI. The Annex II and the RMP version 10.0 are updated accordingly. In addition, the MAH took the opportunity to make a minor editorial update by removing some grey shading from Annex III.				
Variation type IB / EMA/VR/0000356026	Outcome: This was an application for a group of variations. Q.I.e.4 Changes to a post-approval change management protocol (PACMP) - Q.I.e.4.b) Minor changes to a post-approval change management protocol that do not change the strategy defined in the protocol - Accepted Q.II.g.4 Changes to a post-approval change management protocol (PACMP) - Q.II.g.4.b) Minor changes to a post-approval change management protocol that do not change the strategy defined in the protocol - Accepted	13/07/2026			
Variation type IB / EMA/VR/0000350435	Outcome: Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.z Other variation - Accepted	01/07/2026			

PASS / EMA/PASS/0000328042	Outcome:	10/04/2026			
Variation type II / EMA/VR/0000313331	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted	26/02/2026			Not applicable
Variation type IB / EMA/VR/0000315442	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted	13/02/2026			
Variation type IA / EMA/VR/0000323986	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product,	09/02/2026			

	packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted				
Variation type IB / EMA/VR/0000313323	Outcome: B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	30/01/2026			
Variation type II / EMA/VR/0000258227	Outcome: This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c	29/01/2026			Not applicable

	The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.d Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or				

	addition) for the active substance or a starting material/intermediate - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.d Deletion of a non-significant specification parameter				

	(e.g. deletion of an obsolete parameter) - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted - - Accepted				
Variation type IB / EMA/VR/0000310085	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	26/11/2025			
Variation type IB / EMA/VR/0000292821	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	10/11/2025			
Variation type II / EMA/VR/0000264124	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL	16/10/2025	21/11/2025	SmPC and Labelling	The group of variations concern update of efficacy data based on the study JCAR017-BCM-003 and safety data in pooled data for studies TRANSFORM BCM-003, PILOT 17006 and TRANSCEND WORLD, cohort 2 BCM-001. For more information, please

	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study JCAR017-BCM-003; this is a global randomized multicenter phase 3 trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell Non-Hodgkin lymphomas (TRANSFORM). In addition, final study reports for studies 017006 and JCAR017-BCM-001 Cohort 2 are submitted to support the main scope. C.I.4: Update of section 4.8 of the SmPC in order to update information for the safety and immunogenicity based on pooled final data form the three follow up studies: (TRANSFORM BCM-003, PILOT 17006 and TRANSCEND WORLD, cohort 2 BCM-001). In addition, the MAH took the opportunity to				refer to the Summary of Product Characteristics.

	remove the dose verification worksheet statement from the Labelling.				
Variation type II / EMA/VR/0000265024	Outcome: This was an application for a group of variations. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted	16/10/2025	21/11/2025	SmPC, Labelling and PL	Please refer to Scientific Discussion "Breyanzi-H-C-4731- EMA/VR/0000265024"
Variation type II / EMA/VR/0000272242	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.4, 4.7 and 4.8 of the SmPC in order to update the post-treatment safety monitoring information based on clinical trials and real-world data. The Package leaflet section and the annex II are updated in accordance. The applicant	16/10/2025	21/11/2025	SmPC, Annex II and PL	SmPC new text: Patients should be monitored 2 3 times during the first week following infusion, at the qualified treatment centre for signs and symptoms of CRS/neurologic toxicities. Frequency of monitoring after the first week should be carried out at the physician's discretion, and should be continued for at least 2 weeks after infusion. Patients and caregivers should be informed about the potential late onset of neurologic toxicities and instructed to seek immediate medical attention if patients experience any signs or symptoms of neurologic toxicities. Due to the potential for neurologic events, including altered mental status or seizures with Breyanzi, patients receiving

	also took the occasion to update the list of local representatives for Iceland in the package leaflet. Version 9.1 of the RMP has also been submitted.				Breyanzi should refrain from driving or operating heavy or potentially dangerous machines for at least 4 weeks after Breyanzi infusion, or longer at the physician's discretion For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000293528	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	16/09/2025			
Variation type IB / EMA/VR/0000288460	Outcome: This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	02/09/2025			

	B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted				
Variation type IB / EMA/VR/0000290623	Outcome: B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	29/08/2025			
Variation type IB / EMA/VR/0000288030	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) - To update the RMP to add follicular lymphoma patients infused with liso-cel in the post marketing setting in the study population of study JCAR017 BCM-005, based on the updated post-authorization safety study (PASS) protocol that was endorsed by PRAC. In addition, the MAH took the opportunity to implement an editorial change to correct the milestone dates for the Transgene assay service listed in Table 3.3-1, aligning them with the	12/08/2025			To update the RMP to add follicular lymphoma patients infused with liso-cel in the post marketing setting in the study population of study JCAR017 BCM-005, based on the updated post-authorization safety study (PASS) protocol that was endorsed by PRAC.

	European Commission's decision date.				
Variation type IB / EMA/VR/0000273146	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	04/08/2025			
Variation type IB / EMA/VR/0000269488	Outcome: This was an application for a group of variations. B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.c Change to an approved stability protocol - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.c Change	25/07/2025			

	to an approved stability protocol - Withdrawn B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted				
Variation type II / EMA/VR/0000249056	Outcome: B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted	24/07/2025			
PASS / EMA/PASS/0000269320	Outcome:	10/07/2025			
Variation type IA_IN / EMA/VR/0000272241	Outcome: B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	20/05/2025			
Variation type IB / EMA/VR/0000257499	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing	10/04/2025			

	authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z - to provide a consolidated Risk Management Plan (RMP) following a positive CHMP opinion for procedures EMEA/H/C/004731/II/0043/G and EMEA/H/C/004731/IB/0051.				
Variation type IA_IN / EMA/VR/0000246077	Outcome: B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	06/02/2025			
PSUR / EMA/PSUR/0000269003	EURD: PSUSA/00010990/202502 Active substance: lisocabtagene maraleucel / lisocabtagene maraleucel Outcome: Maintenance	04/09/2025			Maintenance