Abecma

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/0000308491	This was an application for a group of variations.	02/12/2025	N/A		

[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).

	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.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				
Variation type IA / EMA/VR/0000312707	This was an application for a group of variations. B.I.d.1.a Re-test period/storage period - B.I.d.1.a.1 Reduction - 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.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate /	17/11/2025	N/A		

	reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type II / EMA/VR/0000293201	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, and 4.7 of the SmPC in order to change the post-approval safety monitoring requirements and driving restrictions after administration of Abecma; Annex II and the Package Leaflet are updated accordingly. The RMP version 5.1 has also been submitted.	13/11/2025		SmPC, Annex II and PL	SmPC new text: Patients should be monitored for the first week following Abecma infusion at the qualified treatment centre for signs and symptoms of CRS. After the first week following infusion, the patient should be monitored at the physician’s discretion. Patients should be counselled to remain within proximity (within 2 hours of travel) of the qualified treatment centre for at least 2 weeks following infusion. Patients and caregivers should be informed about the potential late onset of CRS and instructed to seek immediate medical attention if patients experience any signs or symptoms of CRS at any time. Due to the potential for neurologic adverse reactions, including altered mental status or seizures with Abecma, patients receiving Abecma

					should refrain from driving or operating heavy or potentially dangerous machines for at least 4 weeks after Abecma infusion or longer until resolution of neurologic adverse reactions at the physician's discretion. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000296125	This was an application for a group of variations. 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 B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	03/10/2025	N/A		
Variation type IA_IN / EMA/VR/0000296162	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do	16/09/2025		SmPC	To update section 4.4 of the SmPC to implement the signal recommendations on 'Ciltacabtagene autoleucel; idecabtagene vicleucel; tisagenlecleucel – Progressive multifocal leukoencephalopathy (EPITT no 20153)' adopted at the 10 July 2025 PRAC.

	not require any further assessment - Accepted				
Variation type IB / EMA/VR/0000287399	This was an application for a group of variations. 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 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	12/08/2025	N/A		
Variation type IB / EMA/VR/0000273138	B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.z Other changes - Accepted	06/08/2025		SmPC and PL	
Variation type II / EMA/VR/0000249089	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	24/07/2025	N/A		

	method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted				
Variation type II / EMA/VR/0000248772	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	19/06/2025	N/A		Not applicable
Variation type IB / EMA/VR/0000268521	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	30/05/2025	N/A		
Variation type IB / EMA/VR/0000255967	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	15/04/2025	N/A		
Variation type IB / EMA/VR/0000248058	B.II.h Adventitious Agents Safety - B.II.h.z Other variation - Accepted	04/03/2025	N/A		

PSUR / EMA/PSUR/0000282288	- -				Maintenance