Tecvayli

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 /	This was an application for a variation	04/09/2025	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).

EMA/VR/0000278107	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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				
Variation type IB / EMA/VR/0000273943	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	27/06/2025	N/A		
Variation type II / EMA/VR/0000254941	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 section 4.4 of the SmPC in order	12/06/2025	12/08/2025	SmPC and PL	Not applicable.

	to include the term 'fatal' under the warning for Neurologic Toxicities, including ICANS. In addition, the MAH took the opportunity to introduce minor changes to section 4.2 of the SmPC in order to update the intervals regarding the restarting of teclistamab after a dose delay. Furthermore, the MAH took the opportunity to update the PI with the excipient information on polysorbate following the latest EU Excipients Guideline as well as to update the list of local representatives in the Package Leaflet.				
Variation type IB / EMA/VR/0000272928	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 Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted To extend the due date of the interim report for study 64007957MMY3001 from September 2025 to March 2026 in the RMP.	03/06/2025	N/A		To extend the due date of the interim report for study 64007957MMY3001 from September 2025 to March 2026 in the RMP.
Variation type IA / EMA/VR/0000272695	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted	22/05/2025	N/A		

	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted				
Renewal - 1 year / EMA/R/0000249306	- Renewal - Accepted	25/04/2025	12/08/2025		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Tecvayli, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
Variation type IB / EMA/VR/0000263112	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	24/04/2025	N/A		
PSUR / EMA/PSUR/0000274444	- -				Maintenance.