Talvey

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 /	B.I.b.2 Change in test procedure for active	21/11/2025	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/0000296033	substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Variation type II / EMA/VR/0000280497	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 5.1 of the SmPC in order to update immunogenicity data based on an updated Integrated Summary of Immunogenicity. In addition, the MAH took the opportunity to update the excipient information and warning regarding polysorbate, introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet.	16/10/2025		SmPC and PL	No clinically meaningful impact of anti-talquetamab antibodies has been observed in patients treated with subcutaneous talquetamab monotherapy at 0.4 mg/kg weekly or 0.8 mg/kg every 2 weeks, with or without prior T cell redirection therapy, on the pharmacokinetics, safety, or effectiveness of talquetamab. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000286343	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	26/09/2025		SmPC and PL	

Variation type II / EMA/VR/0000258454	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 4.8 of the SmPC in order to add a new warning on Ataxia/Balance disorder based on post-marketing data. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted.	04/09/2025		SmPC and PL	Not applicable
Variation type II / EMA/VR/0000264615	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.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted Submission of the interim report from study 64407564MMY1001 listed as a Specific Obligation in the Annex II of the Product Information. This is a phase 1/2, first-in-human, open-label, dose escalation study of talquetamab, a humanized GPRC5D x CD3 bispecific antibody, in subjects with relapsed or refractory multiple myeloma. Safety data	04/09/2025		Annex II	Not applicable

	were revised based on the 2-year follow-up analysis for the pivotal RP2D population The Annex II and the RMP version 3.2 are updated accordingly.				
Variation type IB / EMA/VR/0000278107	This was an application for a variation 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	04/09/2025	N/A		
Variation type II / EMA/VR/0000256831	B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	15/05/2025			

Renewal - 1 year / EMA/R/0000249367	- Renewal - Accepted	25/04/2025	11/08/2025		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 TALVEY, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. Clarifications regarding the conclusions from 6 of the 7 pharmacovigilance system inspections of the company should be provided as requested as part of RfSI.
PSUR / EMA/PSUR/0000268940	- -				Maintenance