



Ebvallo

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IA/0010	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	04/03/2024		SmPC	
PSUSA/11028 /202306	Periodic Safety Update EU Single assessment - tabelecleucel	11/01/2024	n/a		PRAC Recommendation - maintenance

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).



IB/0007	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	19/12/2023	22/02/2024	SmPC and Labelling	
IB/0003	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	04/05/2023	n/a		
IB/0004/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	03/05/2023	n/a		
IAIN/0002	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	09/03/2023	22/02/2024	Annex II and PL	
T/0001	Transfer of Marketing Authorisation	20/01/2023	06/02/2023	SmPC, Labelling and PL	