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
PSUSA/11028 /202406	Periodic Safety Update EU Single assessment - tabelecleucel	16/01/2025	n/a		PRAC Recommendation - maintenance
IB/0017	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	17/12/2024	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).

II/0011/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	12/12/2024		SmPC, Annex II and PL	
IB/0015/G	This was an application for a group of variations. 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 B.II.f.1.e - Stability of FP - Change to an approved stability protocol	10/12/2024		SmPC	
IB/0016/G	This was an application for a group of variations.	04/12/2024	n/a		

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IB/0014/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.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	23/10/2024	n/a		
IB/0013	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	16/09/2024	n/a		
PSUSA/11028 /202312	Periodic Safety Update EU Single assessment - tabelecleucel	11/07/2024	n/a		PRAC Recommendation - maintenance
S/0008	First annual re-assessment	30/05/2024	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data

					submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Ebvallo should be maintained.
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
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	09/03/2023	22/02/2024	Annex II and	

	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			PL	
T/0001	Transfer of Marketing Authorisation	20/01/2023	06/02/2023	SmPC, Labelling and PL	