EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CARVYKTI

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/0022	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/07/2023		SmPC	
II/0019	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	20/07/2023	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).

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	control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				
II/0016	B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP	22/06/2023	n/a		
IB/0020	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	19/06/2023	n/a		
IB/0015/G	This was an application for a group of variations. 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 B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	28/04/2023	n/a		
II/0005	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test	30/03/2023	n/a		

	method or a method using a biological reagent for a biological AS				
IB/0014	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	28/03/2023	n/a		
R/0008	Renewal of the marketing authorisation.	26/01/2023	24/03/2023	SmPC, Annex II and PL	The CAT/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 CARVYKTI, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0010/G	This was an application for a group of variations. B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	17/03/2023	n/a		
PSUSA/11000 /202208	Periodic Safety Update EU Single assessment - ciltacabtagene autoleucel	16/03/2023	n/a		PRAC Recommendation - maintenance

N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/03/2023		PL	
IB/0012	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	17/02/2023	n/a		
IB/0011	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	14/02/2023	n/a		
II/0004/G	This was an application for a group of variations. Grouped application comprising two type II variations as follows: - Update of section 4.4 of the SmPC in order to add a new warning on increased risk of severe/fatal COVID-19 infections following Covid-19 signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on a cumulative review of all clinical trials, registries and literature. - Update of section 4.4 of the SmPC in order to add a new warning Risk of severe bleeding in the context of hemophagocytic lymphohistiocytosis syndrome (HLH) following a signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on cumulative review of all clinical trials, registries and literature.	15/12/2022	24/03/2023	SmPC and PL	SmPC new text: Patients who develop HLH may have an increased risk of severe bleeding. Patients treated with CARVYKTI may be at an increased risk of severe/fatal COVID-19 infections. Patients should be counselled on the importance of prevention measures. For more information, please refer to the Summary of Product Characteristics.

	The Package Leaflet is updated accordingly. The RMP version 2.2 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0003	Update of sections 4.4 and 4.8 of the SmPC in order to update the existing warnings on cytokine release syndrome (CRS), neurologic toxicities and grading of related events and to update the list of adverse drug reactions (ADRs) based on previously reviewed data from studies MMY2001 and MMY2003, and an additional internal characterisation of neurotoxicity risk; the Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/12/2022	24/03/2023	SmPC, Labelling and PL	For more information, please refer to the Summary of Product Characteristics.
IB/0007	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	24/11/2022	n/a		
IB/0006	B.I.b.1.b - Change in the specification parameters	10/11/2022	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
II/0002	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	10/11/2022	n/a		
IB/0001	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	11/10/2022	n/a		