Abecma

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
IB/0021	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	16/12/2022	n/a		
II/0020	B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening	15/12/2022	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).

	of the approved in-process test limits, which may have a significant effect on the overall quality of the AS				
II/0019	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	15/12/2022	n/a		
PSUSA/10954 /202203	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0018/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	21/09/2022	n/a		
IB/0017	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	24/08/2022	n/a		
R/0014	Renewal of the marketing authorisation.	22/04/2022	24/06/2022	Annex II	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 Abecma, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. The due date for the remaining SOB referring to study KarMMa 3 (MM 003) has been amended due to a protocol amendment of the study occurred since approval of the Conditional Marketing Authorisation for Abecma, which has prolonged the time for the interim analysis and postponed the final clinical study report of about 6 month.
PSUSA/10954 /202109	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	05/05/2022	n/a		PRAC Recommendation - maintenance
IB/0013	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	21/03/2022	n/a		
IB/0015/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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	03/03/2022	n/a		
II/0010	Update of section 5.1 of the SmPC in order to update efficacy information based on 24 month follow up	27/01/2022	24/06/2022	SmPC and	Summary Based on the 24 months longer follow-up data regarding

	data from the pivotal study submitted during initial MAA (BB2121-MM-001: A Phase 2, Multicenter Study to determine the Efficacy and Safety of bb2121 in Subjects with Relapsed and Refractory Multiple Myeloma) listed as a specific obligation in the Annex II and in the RMP; The annex II is updated with the proposed deletion of the relevant SOB. The RMP version 1.2 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data			Annex II	MRD-negative status and ☐ CR and duration of responses have been updated in section 5.1 of the SmPC. Specific obligation in the frame of the Conditional Marketing authorisation has been considered fulfilled and deleted from annex II of the product information. For more information, please refer to the Summary of Product Characteristics.
II/0002	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	27/01/2022	n/a		
II/0009	Update of sections 4.2 and 4.4 of the SmPC, Annex IID and PIL in order to add statements for the use of Abecma exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab" C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/12/2021	20/01/2022	SmPC, Annex II and PL	SmPC new text The product information has been amended to reflect that in the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, suitable alternative measures to treat CRS instead of tocilizumab must be available prior to infusion. For more information, please refer to the Summary of Product Characteristics.
IB/0012/G	This was an application for a group of variations.	17/01/2022	n/a		

	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation				
II/0005/G	This was an application for a group of variations. 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 B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	16/12/2021	n/a		
IB/0008/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	19/11/2021	n/a		
T/0007	Transfer of Marketing Authorisation	04/11/2021	18/11/2021	SmPC,	

				Labelling and PL	
IB/0006/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	16/11/2021	n/a		
II/0001/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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 method or a method using a biological reagent for a biological AS	11/11/2021	n/a		
IB/0003	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	05/10/2021	n/a		
IAIN/0004/G	This was an application for a group of variations.	28/09/2021	18/11/2021	SmPC, Annex II, Labelling	

	A.1 - Administrative change - Change in the name and/or address of the MAH 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			and PL	