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
IAIN/0057	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	22/11/2024		Annex II and PL	

[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).

PSUSA/10954 /202403	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	31/10/2024	n/a		PRAC Recommendation - maintenance
II/0047	- To update section 6.6 of the SmPC - "Special precautions for disposal and other handling", and corresponding section of the Package Leaflet, to clarify dose preparation and administration instructions of the thawed finished product (IV administration set fitted with a non-leukodepleting in-line filter which can be used to reduce visible cellular aggregates that do not disperse after gentle manual mixing). In addition, the labelling has been updated to include information to appear on the infusion bag – chain of identity label and the package leaflet has been updated to include the local representatives of the MAH. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	19/09/2024		SmPC, Labelling and PL	Section 6.6 of the SmPC "Special precautions for disposal and other handling" was updated to clarify the dose preparation, thawing and administration instructions of the thawed finished product. For more information, please refer to the Summary of Product Characteristics. The PL has been updated accordingly. In addition, the labelling has been updated to include information to appear on the infusion bag – chain of identity label and the PL has been updated to include the local representatives of the MAH.
IAIN/0055	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/09/2024		SmPC, Annex II and PL	
IB/0054	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	02/08/2024	n/a		
II/0048	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the	25/07/2024	n/a		Not applicable

	change requires an assessment of comparability				
IB/0050	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	11/07/2024	n/a		
PSUSA/10954 /202309	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	25/04/2024	20/06/2024	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10954/202309.
IB/0052	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	16/05/2024	n/a		
IB/0051	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	16/05/2024	n/a		
IB/0049	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	15/05/2024	n/a		
IB/0046	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	25/03/2024	n/a		
II/0031	Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38	25/01/2024	19/03/2024	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Abecma-H-C-4662-II-0031'

	antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.2 of the RMP has also been submitted. Furthermore, the PI is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IA/0045/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.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	22/02/2024	n/a		

	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IB/0041	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	14/12/2023	n/a		
IB/0042	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	07/12/2023	n/a		
IB/0043/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.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	13/11/2023	n/a		
PSUSA/10954 /202303	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	26/10/2023	n/a		PRAC Recommendation - maintenance

IA/0040	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/09/2023	06/02/2024	SmPC	
IB/0039	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	30/08/2023	n/a		
IB/0038/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/08/2023	n/a		
II/0037/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.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	20/07/2023	n/a		
II/0034	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	20/07/2023	n/a		

	biological/immunological product				
PSUSA/10954 /202209	Periodic Safety Update EU Single assessment - idecabtagene vicleucel	26/04/2023	23/06/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10954/202209.
II/0032/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.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 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 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 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	22/06/2023	n/a		

	biological AS 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				
IB/0035	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	08/06/2023	n/a		
R/0029	Renewal of the marketing authorisation.	26/04/2023	08/06/2023		The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, are 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.
IB/0033	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	01/06/2023	n/a		
IB/0030/G	This was an application for a group of variations. 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	25/05/2023	n/a		

	data 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 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 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 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 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 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				
II/0027	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	26/04/2023	n/a		
II/0026	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a	30/03/2023	n/a		

	biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol				
II/0022/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.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.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	30/03/2023	n/a		
IB/0025	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	30/01/2023	n/a		

IB/0024/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	27/01/2023	n/a		
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 of the approved in-process test limits, which may have a significant effect on the overall quality of the AS	15/12/2022	n/a		
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	21/09/2022	n/a		

	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				
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 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	27/01/2022	24/06/2022	SmPC and Annex II	Summary Based on the 24 months longer follow-up data regarding 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. 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	17/01/2022	n/a		
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	11/11/2021	n/a		

	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				
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. 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	28/09/2021	18/11/2021	SmPC, Annex II, Labelling and PL	