EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Blenrep (EXP)

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/10869 /202302	Periodic Safety Update EU Single assessment - belantamab mafodotin	31/08/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10869 /202208	Periodic Safety Update EU Single assessment - belantamab mafodotin	30/03/2023	26/05/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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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					PSUSA/10869/202208.
IB/0018	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	30/03/2023	26/05/2023	SmPC	Product information section 6.3 is updated to reflect the shelf-life extension of the finished product BLENREP 100 mg powder for concentrate for solution for infusion (EU/1/20/1474/001) as packaged for sale from 3 years to 4 years.
IB/0016/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 data 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	07/02/2023	n/a		
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/09/2022	26/05/2023	Annex II	
PSUSA/10869 /202202	Periodic Safety Update EU Single assessment - belantamab mafodotin	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0013	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	16/08/2022	n/a		
IB/0012	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/07/2022	n/a		

R/0010	Renewal of the marketing authorisation.	22/04/2022	29/06/2022		The 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 Blenrep, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. SmPC section 5.3 Preclinical data is being updated to reflect new data from the ocular toxicity study in rabbits (Report 2021N465838). The following sentence is added: "Inflammation of the corneal stroma correlating with superficial haze and vascularisation was observed in rabbits". In addition, the MAH has amended the ATC code (L01FX15) according to the updated WHO classification.
PSUSA/10869 /202108	Periodic Safety Update EU Single assessment - belantamab mafodotin	24/03/2022	30/05/2022		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10869/202108.
IB/0009/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	25/02/2022	n/a		
IB/0008/G	This was an application for a group of variations.	11/02/2022	n/a		

	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.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data 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				
II/0006/G	This was an application for a group of variations. Amendments to the marketing authorisation In view of the data submitted with the group of variations, amendments to Annex(es) I, IIIA and IIIB are recommended. 3. EPAR changes The table in Module 8b of the EPAR will be updated as follows: Scope Please refer to the Recommendations section above 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	13/01/2022	30/05/2022	SmPC, Labelling and PL	SmPC new text Section 4.4: Warning on Pneumonitis is added: Cases of pneumonitis from spontaneous reports and named patient programs, including fatal events, have been observed with BLENREP although a causal association has not been established. Evaluation of patients with new or worsening unexplained pulmonary symptoms (e.g. cough, dyspnea) should be performed to exclude possible pneumonitis. In case of suspected Grade 3 or higher pneumonitis, BLENREP should be withheld. If Grade 3 or higher pneumonitis is confirmed, appropriate treatment should be initiated. BLENREP should only be resumed after an evaluation of the benefit and risk. Section 4.8: Albuminuria is added as an AE with frequency Common and incidences 2% at any grade and 1% at grade 3-4

	new quality, preclinical, clinical or pharmacovigilance data				For more information, please refer to the Summary of Product Characteristics.
IB/0007/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.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 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	13/12/2021	30/05/2022	SmPC	
PSUSA/10869 /202102	Periodic Safety Update EU Single assessment - belantamab mafodotin	02/09/2021	n/a		PRAC Recommendation - maintenance
R/0003	Renewal of the marketing authorisation.	22/04/2021	21/06/2021	SmPC	
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	27/01/2021	21/06/2021	SmPC, Annex II and PL	
IB/0001/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	06/01/2021	21/06/2021	SmPC	

	re-test period/storage period supported by real time data 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.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				