Lamzede

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
R/0029	Renewal of the marketing authorisation.	10/11/2022	13/01/2023	SmPC, Annex II, Labelling and PL	
PSUSA/10677 /202203	Periodic Safety Update EU Single assessment - velmanase alfa	27/10/2022	n/a		PRAC Recommendation - maintenance

[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/0027	Update of section 4.2 the SmPC in order to include the home infusion statement, following the assessment of PSUSA/00010677/202009, based on results from LAMAN-07, Sparkle and Italian Patient Support Program (PSP). The Package Leaflet and Annex II are updated accordingly. The RMP version 9.3 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/07/2022	13/01/2023	SmPC, Annex II and PL	Infusion of Lamzede at home may be considered for patients who are tolerating their infusions well. The decision to have a patient move to home infusion should be made after evaluation and recommendation by the treating physician. Appropriate training should be given by the treating physician and/or nurse to the patient and/or caregiver prior to initiation of home infusion. For more information, please refer to the Summary of Product Characteristics.
S/0025	Annual re-assessment.	23/06/2022	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 Lamzede should be maintained.
II/0023/G	This was an application for a group of variations. 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.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	05/05/2022	n/a		

IB/0026	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	28/04/2022	n/a		
PSUSA/10677 /202109	Periodic Safety Update EU Single assessment - velmanase alfa	07/04/2022	n/a		PRAC Recommendation - maintenance
IB/0022	B.II.z - Quality change - Finished product - Other variation	15/11/2021	n/a		
II/0018	Update of sections 4.4, 4,8 and 5.1 of the SmPC in order to amend an existing warning on immunogenicity, update the summary of the safety profile, add cyanosis to the list of adverse drug reactions (ADRs) with frequency 'common', add the information that the safety profile observed in children under age 6 is consistent with what was observed in previous studies, update the pharmacodynamic properties. These proposed SmPC updates are based on the final results of rhLAMAN-08 study, which is listed as an Annex II study in the RMP, and is a 24-month multi-centre, open-label phase II trial investigating the safety and efficacy of repeated velmanase alfa (recombinant human alpha-mannosidase) treatment in paediatric patients <6 years if age with alpha-mannosidosis, The Package Leaflet is being update accordingly. The RMPv8.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with QRD template v10.1 and v10.2.	16/09/2021	03/11/2021	SmPC, Annex II, Labelling and PL	Based on the final results of rhLAMAN-08 study, which was a 24-month open-label phase II trial investigating the safety and efficacy of repeated velmanase alfa treatment in paediatric patients below 6 years of age with alpha-mannosidosis, SmPC sections 4.4, 4,8 and 5.1 are being updated to amend an existing warning on immunogenicity, update the summary of the safety profile and add cyanosis as an ADR with frequency 'common', and update the pharmacodynamic properties in children below 6 years of age. For more information, please refer to the Summary of Product Characteristics.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10677 /202103	Periodic Safety Update EU Single assessment - velmanase alfa	28/10/2021	n/a		PRAC Recommendation - maintenance
IA/0021/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.b - Change to in-process tests or limits	01/10/2021	n/a		

	applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits				
S/0019	Annual re-assessment.	24/06/2021	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 Lamzede should be maintained.
PSUSA/10677 /202009	Periodic Safety Update EU Single assessment - velmanase alfa	09/04/2021	n/a		PRAC Recommendation - maintenance
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/10/2020	05/07/2021	PL	
PSUSA/10677 /202003	Periodic Safety Update EU Single assessment - velmanase alfa	29/10/2020	n/a		PRAC Recommendation - maintenance
II/0012/G	This was an application for a group of variations. B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the	03/09/2020	n/a		

	approved specifications limits range for the 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/0015	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	07/08/2020	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	15/07/2020	05/07/2021	Annex II	
S/0011	Annual re-assessment.	25/06/2020	n/a		
PSUSA/10677 /201909	Periodic Safety Update EU Single assessment - velmanase alfa	17/04/2020	n/a		PRAC Recommendation - maintenance
II/0007	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	12/12/2019	n/a		
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/12/2019	n/a		
PSUSA/10677 /201903	Periodic Safety Update EU Single assessment - velmanase alfa	03/10/2019	n/a		PRAC Recommendation - maintenance

IA/0008	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	17/09/2019	n/a		
IB/0006	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	12/07/2019	n/a		
S/0004	Annual re-assessment.	27/06/2019	n/a		
PSUSA/10677 /201809	Periodic Safety Update EU Single assessment - velmanase alfa	11/04/2019	n/a		PRAC Recommendation - maintenance
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2018	04/10/2019	PL	
IB/0001	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	05/10/2018	04/10/2019	SmPC	