OXERVATE

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/0037	Renewal of the marketing authorisation.	27/01/2022	28/03/2022	SmPC, Annex II, Labelling and PL	
PSUSA/10624 /202107	Periodic Safety Update EU Single assessment - cenegermin	10/02/2022	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).

PSUSA/10624 /202101	Periodic Safety Update EU Single assessment - cenegermin	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0035/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 A.6 - Administrative change - Change in ATC Code/ATC Vet Code	06/08/2021	28/03/2022	SmPC	
IB/0034	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	02/07/2021	n/a		
IB/0032	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	23/06/2021	n/a		
IA/0033	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	01/06/2021	n/a		
PSUSA/10624 /202007	Periodic Safety Update EU Single assessment - cenegermin	11/02/2021	n/a		PRAC Recommendation - maintenance
IB/0030	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	03/02/2021	n/a		

IB/0029	B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS	29/01/2021	n/a		
IB/0028	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	15/12/2020	n/a		
PSUSA/10624 /202001	Periodic Safety Update EU Single assessment - cenegermin	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0025/G	This was an application for a group of variations. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	11/05/2020	n/a		
IB/0024	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	11/03/2020	n/a		
IB/0022/G	This was an application for a group of variations.	07/02/2020	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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				
IB/0023/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.z - Change to in-process tests or limits applied during the manufacture 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	06/02/2020	n/a		
PSUSA/10624 /201907	Periodic Safety Update EU Single assessment - cenegermin	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0021	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	17/12/2019	n/a		
IB/0019	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	22/11/2019	n/a		

IB/0017/G	This was an application for a group of variations. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	23/07/2019	n/a		
PSUSA/10624 /201901	Periodic Safety Update EU Single assessment - cenegermin	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0016	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	27/06/2019	n/a		
IB/0015	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	11/04/2019	n/a		
IA/0013/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.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of	06/02/2019	n/a		

	specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10624 /201807	Periodic Safety Update EU Single assessment - cenegermin	17/01/2019	n/a		PRAC Recommendation - maintenance
IB/0012	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	04/01/2019	n/a		
IB/0010/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.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	30/07/2018	n/a		
PSUSA/10624 /201801	Periodic Safety Update EU Single assessment - cenegermin	12/07/2018	n/a		PRAC Recommendation - maintenance
IB/0009	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting	18/06/2018	n/a		

	material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method				
IB/0007	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	05/06/2018	n/a		
IB/0008	B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	04/06/2018	n/a		
IB/0006/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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	16/04/2018	n/a		
IB/0004/G	This was an application for a group of variations. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	19/03/2018	n/a		
II/0002	B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new	18/01/2018	n/a		

	bioequivalence study				
IA/0003	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	05/01/2018	n/a		
IB/0001	B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	30/10/2017	n/a		