Saphnelo

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/0019	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/08/2024	n/a		
PSUSA/10980 /202307	Periodic Safety Update EU Single assessment - anifrolumab	21/03/2024	16/05/2024	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).

					PSUSA/10980/202307.
IB/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/03/2024	16/05/2024	SmPC and PL	
IA/0014	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	30/01/2024	16/05/2024	SmPC	
IB/0012/G	This was an application for a group of variations. B.I.c.1.c - Change in immediate packaging of the AS - Liquid ASs (non sterile) B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	24/10/2023	n/a		
IB/0011	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/09/2023	n/a		
II/0007	Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC	14/09/2023	16/05/2024	SmPC and PL	Patients who completed D3461C00004 [study 04] and

	based on final results from study D3461C00009 listed as an additional pharmacovigilance activity in the RMP; this is a multicentre, randomised, double-blind, placebo-controlled Phase III extension study to characterise the long-term safety and tolerability of anifrolumab in adult subjects with active systemic lupus erythematosus. In addition, the MAH took the opportunity to implement minor changes to sections 4.2 and 6.6 of the SmPC and to the Package Leaflet. In addition, the MAH took the opportunity to update the list of local representatives in the Netherlands in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				study D3461C00005 [study 05] (feeder trials) through Week 52 were eligible to continue on treatment in a randomised, double-blind, placebo-controlled, 3-year Long Term Extension (study D3461C00009). Following long-term observations, the clearance of anifrolumab was found to be stable in years 2 through 4 on treatment. Long-term efficacy was evaluated in patients who received anifrolumab 300 mg or placebo in a feeder trial and continued to receive the same treatment in the LTE (anifrolumab N=257; placebo N=112). Of these, 69% of patients who received anifrolumab (177/257) and 46% of patients who received placebo (52/112) completed a total of 4 years on treatment. At Week 208, the mean SLEDAI-2K score (SE) was 3.4 (0.25) and 4.0 (0.46) in patients who received anifrolumab (n=140) and placebo (n=44) respectively. The overall long-term safety profile of anifrolumab was consistent with the 52 week trials. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10980 /202301	Periodic Safety Update EU Single assessment - anifrolumab	31/08/2023	n/a		PRAC Recommendation - maintenance
IAIN/0010	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	12/07/2023	16/05/2024	Annex II and PL	
IA/0008	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	23/03/2023	n/a		

	(excluding manufacturer for batch release)				
PSUSA/10980 /202207	Periodic Safety Update EU Single assessment - anifrolumab	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/12/2022	n/a		
IA/0006/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	19/12/2022	n/a		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/10/2022	16/05/2024	PL	

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	05/05/2022	n/a		
IB/0001	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	11/04/2022	n/a		