ASPAVELI

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/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure	05/04/2024		SmPC	

[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).

	(including replacement or addition) B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)				
IB/0016/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - 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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	15/03/2024	n/a		
II/0015	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	14/03/2024	n/a		
PSUSA/10974 /202305	Periodic Safety Update EU Single assessment - pegcetacoplan	30/11/2023	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.z - Quality change - Finished product - Other variation	31/10/2023	n/a		

IB/0014	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits	13/10/2023	n/a		
PSUSA/10974 /202211	Periodic Safety Update EU Single assessment - pegcetacoplan	08/06/2023	n/a		PRAC Recommendation - maintenance
IB/0009	B.I.z - Quality change - Active substance - Other variation	04/01/2023	n/a		
IB/0007	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	20/12/2022	n/a		
IA/0008/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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch	15/12/2022	n/a		

	size 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				
PSUSA/10974 /202205	Periodic Safety Update EU Single assessment - pegcetacoplan	01/12/2022	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	30/08/2022	n/a		
IA/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	30/08/2022	n/a		
II/0002	Update of sections 4.2, 4.8, 5.1, 5.2 of the SmPC based on final results from study APL2-302 (Pegasus) listed as a category 3 study in the RMP; this is a global, Phase 3, prospective, randomised, multicentre, open-label, active-comparator–	19/05/2022	15/02/2023	SmPC and PL	Update of sections 4.4, 4.8, 5.1, 5.2 of the SmPC to reflect efficacy and safety results from the final study APL2-302, including the 48 weeks data. Results of the key efficacy analyses of (OLP) confirm the results observed during the 16-week randomized

	controlled study in 80 subjects. The objective was to confirm treatment efficacy and safety of pegcetacoplan monotherapy for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH). The submission of this study addresses MEA 001. The Package Leaflet is updated accordingly. The RMP version 1.0 has been agreed. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				completion phase (RCP) and suggest an improvement in Paroxysmal Nocturnal Hemoglobinuria (PNH) markers. The PK analysis within OLP showed that therapeutic concentrations of pegcetacoplan were maintained for up to Week 48. The Package Leaflet (PL) was updated accordingly. For more information, please refer to the Summary of Product Characteristics.
IB/0003	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	21/02/2022	15/02/2023	SmPC	
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/12/2021	n/a		