ASPAVELI

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II /		07/05/2026			

[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).

EMA/VR/0000333829	Outcome: C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.c) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the holder where significant assessment by the competent authority is required - Accepted Submission of an updated RMP (version 5.1) in order to revise the patient number in the category 3 post-authorization safety study (PASS) Sobi.PEGCET-301 and the milestone date for the clinical study report for the Category 3 study APL2-307.				
Variation type II / EMA/VR/0000313224	Outcome: This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b	29/01/2026			

	Tightening of specification limits - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted				
Variation type II / EMA/VR/0000248937	Outcome: C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for Aspaveli, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicenter study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients	11/12/2025	15/01/2026	SmPC and PL	Please refer to scientific discussion 'Aspaveli-H-C-005553-II-EMA/VR/0000248937'

	diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. As a consequence, sections 4.1, 4.2, 4.8, 4.9, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP is approved. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the PI is brought in line with the latest QRD template version 10.4.				
Variation type IB / EMA/VR/0000312476	Outcome: B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	01/12/2025			
Variation type II / EMA/VR/0000290246	Outcome: B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.3 Spacer device for metered dose inhalers or other device which may have a significant impact	16/10/2025	15/01/2026	SmPC and PL	The SmPC sections 4.2 and 6.6 has been updated as follows: Addition of instructions and precautions to use the new commercially available on-body (abdominal) Class IIb medical device for subcutaneous infusion. The PL has been updated accordingly.

	on the delivery of the active substance in the product (e.g. nebuliser) - Accepted				
Variation type IA_IN / EMA/VR/0000275191	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	27/05/2025			
Variation type IB / EMA/VR/0000254588	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b	22/04/2025			

	Tightening of specification limits - Accepted				
Variation type IA / EMA/VR/0000258001	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product,	06/04/2025			

	packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
PSUR / EMA/PSUR/0000248510	EURD: PSUSA/00010974/202411 Active substance: pegcetacoplan Outcome: Maintenance	05/06/2025			Maintenance