Hympavzi

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 /	Outcome:	26/03/2026	11/05/2026	SmPC and PL	

[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/0000304590	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 routine prophylaxis of bleeding episodes in patients 12 years of age and older with haemophilia A with factor VIII inhibitors or haemophilia B with factor IX inhibitors for HYMPAVZI, based on final results from study B7841005 and interim results from supportive study B7841007. Study B7841005 this is an open-label study in adolescent and adult severe (coagulation factor activity ≤2%) with or without inhibitors comparing standard treatment to PF-06741086 Prophylaxis. Study B7841007 is an open-label extension study to evaluate the long-term safety, tolerability, and efficacy of marstacimab prophylaxis in severe (coagulation factor activity <1%) haemophilia A participants with or without inhibitors or moderately severe to severe haemophilia B participants (coagulation factor activity ≤2%) with or without inhibitors. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted.				

Variation type IB / EMA/VR/0000334711	Outcome: Q.II.e.6.a) Introduction of a new pack size or change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Q.II.e.6.a.2 Change outside the range of the currently approved pack sizes - Accepted	18/03/2026	11/05/2026	SmPC, Labelling and PL	
Variation type II / EMA/VR/0000279720	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC in order to correct the ABR values based on interim results from Phase 3 studies B7841005 and B7841007.	11/12/2025	11/05/2026	SmPC	
Variation type II / EMA/VR/0000292758	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or	06/11/2025			

	addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted				
Variation type IB / EMA/VR/0000294888	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted	25/09/2025			
Variation type II / EMA/VR/0000268024	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add information regarding thromboembolic events and to add "thrombosis" to the list of adverse drug reactions (ADRs) with frequency uncommon based on a review of clinical data, post marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes and corrections to the PI, including Annex II.	04/09/2025	11/05/2026	SmPC, Annex II and PL	Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add information regarding thromboembolic events and to add "Thromboembolic events (thrombosis)" to the list of adverse drug reactions (ADRs) with frequency uncommon based on a review of clinical data, post marketing data and literature. A patient card is also introduced specifically to highlight the risk of thromboembolism. Please refer to Scientific Discussion 'Hympavzi EMA/VR/0000268024' For more information, please refer to the Summary of Product Characteristics.

Variation type IB / EMA/VR/0000263723	Outcome: This was an application for a group of variations. 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.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 B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	28/04/2025	11/05/2026	SmPC and PL	

PSUR / EMA/PSUR/0000321516	EURD: PSUSA/00011101/202510 Active substance: marstacimab Outcome: Maintenance	07/05/2026			Maintenance
PSUR / EMA/PSUR/0000282253	EURD: PSUSA/00011101/202504 Active substance: marstacimab Outcome: Maintenance	30/10/2025			Maintenance