Winrevair

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:	07/05/2026		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).

EMA/VR/0000332803	C. Safety, efficacy, pharmacovigilance changes - C.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 4.8 of the SmPC in order to include cumulative long-term safety data based on the third Safety Update Report (SUR3) for an ongoing open-label follow-up study of the long-term safety and efficacy of sotatercept (SOTERIA).				
Variation type II / EMA/VR/0000315667	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 update efficacy and safety information based on the final results from the study MK-7962-005 (HYPERION). MK-7962-005 (HYPERION) is a Phase 3, randomized, double-blind, placebo-controlled study designed to evaluate the effect of sotatercept in participants who had received the diagnosis less than 1 year earlier, had an intermediate or high risk of death, and were receiving double or triple background	07/05/2026		SmPC and PL	The SmPC sections 4.4, 4.8, are updated regarding undesirable effects and section 5.1 is updated regarding efficacy data based on the final results from the study MK-7962-005 (HYPERION). Sections 4.4 and 4.8 are also updated considering the recently approved revised SmPC based on the results of the ZENITH study. For more information, please refer to the Summary of Product Characteristics.

	therapy. Sections 4.4 and 4.8 are also revised based on the results of the ZENITH study. The RMP version 3.0 has also been approved. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.				
Variation type II / EMA/VR/0000319745	Outcome: This was an application for a group of variations. 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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted 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.e The change relates to a biological active substance or a	30/04/2026		Annex II	The Annex II has been updated to include the newly added manufacturer of the biological active substance (Samsung Biologics Co. Ltd, Republic of Korea).

	starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.c The change requires assessment of the comparability of a biological/immunological active substance - Accepted				
Variation type IB / EMA/VR/0000335114	Outcome: Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted	24/03/2026		SmPC	
Variation type II / EMA/VR/0000272214	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 4.8 of the SmPC in order to add "Intrapulmonary shunt" to the list of adverse drug reactions (ADRs) with frequency uncommon based on post-marketing data; the Package Leaflet is	26/02/2026		SmPC and PL	Section 4.8 of the SmPC has been updated to reflect that right-to-left intrapulmonary shunting has been reported with frequency uncommon in participants who developed worsening hypoxemia despite improved PAH haemodynamics. SmPC new text For more information, please refer to the Summary of Product Characteristics.

	updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The Dutch patient leaflet for the "Driving and using machines" statement has been revised as agreed with CBG-MEB.				
Variation type IB / EMA/VR/0000324945	Outcome: Q.I.b.3 Change to an in-house reference standard/preparation for a biological active substance - Q.I.b.3.e) Other change to the qualification protocol for the prepartation/replacement of an in-house reference standard or preparation - Accepted	09/02/2026			
Variation type II / EMA/VR/0000278021	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 in combination with other pulmonary arterial hypertension (PAH) therapies treatment of adult patients with PAH World Health Organisation Functional Class IV for WINREVAIR, based on interim results from study ZENITH (also referred as MK-7962-006 and A011-14); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate sotatercept when added to	11/12/2025	19/01/2026	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Winrevair-H-C-5647-II-EMA/VR/0000278021'

	maximum tolerated background therapy in participants with pulmonary arterial hypertension (PAH) World Health Organization (WHO) Functional Class (FC) III or FC IV at high risk of mortality; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH removed the first PSUR commitment following 6 months post authorisation as it has already been fulfilled. As part of the application, the MAH is requesting a 1-year extension of the market protection.				
Variation type IB / EMA/VR/0000301939	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.c Addition of a new specification parameter to the specification with its corresponding test method - 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	26/11/2025			

	Tightening of specification limits - Accepted				
PSUR / EMA/PSUR/0000282250	EURD: PSUSA/00011076/202503 Active substance: sotatercept Outcome: Variation In view of available data on pericardial effusion from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship with improvement of functional status or haemodynamics and in view of a plausible mechanism of action, the PRAC considers a causal relationship between sotatercept and pericardial effusion is at least a reasonable possibility. The PRAC concluded that the product information of products containing sotatercept should be amended accordingly.	13/11/2025	08/01/2026	SmPC and PL	Variation
Variation type IA / EMA/VR/0000284673	Outcome: B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted	07/07/2025			
Variation type IB / EMA/VR/0000263625	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7	01/05/2025			

	Deletion of manufacturing sites for an active substance, intermediate or finished product, 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 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 Tightening of specification limits - Accepted				
Variation type IA / EMA/VR/0000262658	Outcome: 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	09/04/2025			

	Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000246288	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z (IB) - To update the Product Information to: -remove reference to section 5.3 in section "4.2 Posology and method of administration" of SmPC as it is not relevant to the paediatric population; -clarify the information on disposal measures as the local requirements can be different in each EU Member State; -update the image details/positioning in the mock-ups for cartons and in the Instructions for Use (1 vial/2 vial), in accordance with the mock-ups reviewed and approved by the Agency. - update the list of local representatives. Furthermore, the Marketing Authorisation Holder has taken the opportunity to implement editorial corrections in the local translations.	28/03/2025	08/01/2026	SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000317685	EURD: PSUSA/00011076/202509 Active substance: sotatercept Outcome: Maintenance	10/04/2026			Maintenance