TEZSPIRE

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:	11/06/2026			

[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/0000321455	This was an application for a group of variations. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted Grouped application comprised of two Type II Variations, as follows: C.I.13: Submission of the report from study D5180C00024 (SUNRISE) listed as a category 3 study in the RMP. This is a randomised, double-blind, parallel-group, placebo-controlled 28-week phase 3 efficacy and safety study of tezepelumab in reducing oral corticosteroid use in adults with oral corticosteroid dependent asthma. The RMP version 7.2 has also been updated accordingly. C.I.11: Submission of an updated RMP version 7.2 in order to add study D5241C00006 (EMBARK) and study D5241C00007 (JOURNEY) as additional pharmacovigilance activities to				

	further characterize the important potential risks: "Serious infections" and "Malignancies".				
Variation type II / EMA/VR/0000245013	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 Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. 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. The updated RMP version 6.2 is acceptable. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline.	18/09/2025	20/10/2025	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Tezspire-H-C-5588-II- EMAVR0000245013'
Variation type IB / EMA/VR/0000284900	Outcome: B.I.b.1 Change in the specification parameters and/or limits of an active	11/08/2025			

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - 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 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.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.a Tightening of specification limits - 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 IB / EMA/VR/0000269627	Outcome: This was an application for a group of	25/07/2025	20/10/2025	PL	

	variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted 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.z Other changes - Accepted B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.a Change that affects the product information - Accepted				
Variation type II / EMA/VR/0000262075	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted Submission of the final report from study D5180C00021 listed as a category 3 study in the RMP. This is a regional, multicentre, randomised, double-blind, placebo controlled, parallel group, phase 3 study to	10/07/2025			

	evaluate the efficacy and safety of tezepelumab in adults with severe uncontrolled asthma (DIRECTION). The submitted RMP version 5.2 is acceptable.				
Variation type IB / EMA/VR/0000275188	Outcome: B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	26/06/2025			
Variation type IB / EMA/VR/0000253536	Outcome: 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.z Other changes - Accepted	19/03/2025			
PSUR / EMA/PSUR/0000257896	EURD: PSUSA/00011015/202412 Active substance: tezepelumab Outcome: Maintenance	10/07/2025			Maintenance