TEZSPIRE

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
PSUSA/11015 /202406	Periodic Safety Update EU Single assessment - tezepelumab	16/01/2025	n/a		PRAC Recommendation - maintenance
II/0013/G	This was an application for a group of variations. A grouped application consisting of:	28/11/2024	n/a		

[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).

	Type II (C.I.11.b): Submission of an updated RMP in order to remove the SUNRISE study (D5180C00024) from the RMP due to discontinuation of the study. This is a Phase 3, randomised, double-blind, parallel-group, placebo-controlled, multicentre study to evaluate the efficacy and safety of tezepelumab 210 mg Q4W administered SC for 28 weeks using an accessorised pre-filled syringe, compared with placebo in reducing OCS use in OCS-dependent adult asthma participants. In addition, the MAH took the opportunity to implement updates to the Targeted Safety Questionnaires (TSQs) and to the Module SI of the RMP to bring it up to date. Type IB (C.I.11.z): Submission of an updated RMP in order to remove the DESTINATION study (D5180C00018) following procedure EMEA/H/C/005588/II/0004. Type IB (C.I.11.z): Submission of an updated RMP in order to propose changes to the study design and objectives for the Pregnancy PASS (D5180R00010), following procedure EMEA/H/C/005588/MEA/001.2. Type IB (C.I.11.z): Submission of an updated RMP in order to propose changes to the study design and objectives for the Cardiac PASS (D5180R00024), following procedure EMEA/H/C/005588/MEA/005. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				

	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
IA/0014/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	31/07/2024	n/a		
PSUSA/11015 /202312	Periodic Safety Update EU Single assessment - tezepelumab	11/07/2024	n/a		PRAC Recommendation - maintenance
PSUSA/11015 /202306	Periodic Safety Update EU Single assessment - tezepelumab	11/01/2024	n/a		PRAC Recommendation - maintenance

II/0009/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.z - Quality change - Active substance - Other variation B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	11/01/2024	16/09/2024	Annex II	Annex II and the PL have been updated.
IAIN/0011	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	06/10/2023	16/09/2024	Annex II and PL	
PSUSA/11015 /202212	Periodic Safety Update EU Single assessment - tezepelumab	20/07/2023	15/09/2023	SmPC and PL	Please refer to TEZSPIRE-EMEA/H/C/PSUSA/00011015/202212 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
II/0008	Update of section 4.5 of the SmPC in order to include information relating to the humoral antibody responses induced by the seasonal influenza virus based on final results from study VECTOR (D5180C00031); this is a multicenter, randomised,	20/07/2023	15/09/2023	SmPC	Update of SmPC section 4.5 to inform healthcare professionals that in a randomised, double blind, parallel group study of 70 patients aged between 12 and 21 years with moderate to severe asthma, tezepelumab treatment did not affect the humoral antibody responses induced by

	double-blind, parallel group, placebo-controlled, phase IIIb study to evaluate the potential effect of tezepelumab on the humoral immune response to seasonal quadrivalent influenza vaccination in adolescent and young adult participants with moderate to severe asthma. In addition, the MAH took the opportunity to implement editorial changes to section 5.1 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				seasonal quadrivalent influenza vaccination. For more information, please refer to the Summary of Product Characteristics.
IB/0007	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	18/04/2023	15/09/2023	SmPC, Labelling and PL	
II/0004	Submission of the final report detailing the extended follow-up data from study D5180C00018 (DESTINATION) listed as a category 3 study in the RMP; this is a multicentre, randomised, double-blind, placebo-controlled, parallel group, long term extension study designed to evaluate the safety and efficacy of 210 mg Q4W subcutaneous of tezepelumab in adults and adolescents with severe uncontrolled asthma for up to 2 continuous years of treatment. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	30/03/2023	n/a		Based on the extended follow-up data from study D5180C00018 (DESTINATION), there was no apparent change to the safety profile of tezepelumab. No new safety concerns were identified.

IAIN/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/01/2023	n/a		
II/0001	B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	12/01/2023	15/09/2023	SmPC, Labelling and PL	The SmPC Sections 1, 2, 3, 4.2, 6.4, 6.5, 6.6, 8 and 9 of the SmPC were updated in order to add a new pre-filled pen presentation. The Labelling and the PL have been updated accordingly.
IB/0002	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	07/11/2022	15/09/2023	SmPC, Labelling and PL	
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/10/2022	n/a		