Olumiant

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 IB /	This was an application for a group of	19/12/2025		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/0000316570	variations. A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - Accepted C.I.3.z To include in SmPC section 4.4 the risk of "opportunistic infections" following the outcome of an Art. 46 procedure. A.1 To change the address of the marketing authorisation holder, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ Utrecht, the Netherlands to Orteliuslaan 1000, 3528 BD Netherlands. The MAH has also taken the opportunity to remove the QR code from the annexes due to lack of use.			Labelling and PL	
Variation type II / EMA/VR/0000266452	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not	10/07/2025	N/A		

	specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from the non-interventional Study I4V-MC-B025 listed as a category 3 study in the RMP. This is a rheumatologist and dermatologist survey to assess the effectiveness of the risk minimisation measures (RMM) for Olumiant, a JAK1/2 inhibitor. The RMP version 25.1 has also been submitted. In addition, the MAH took the opportunity to request an extension to the PASS commitment date for non-interventional Study I4V-MC-B038 (B038).				
PSUR / EMA/PSUR/0000268999	- -				Maintenance