Lyvdelzi

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
Renewal - 1 year /	- Renewal - Accepted	16/10/2025	05/12/2025		

[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/R/0000290389	Renewal of marketing authorisation				
Variation type II / EMA/VR/0000282041	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 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study CB8025-21838 listed as a category 3 study in the RMP. This is an open-label study following oral dosing of seladelpar to subjects with primary biliary cholangitis (PBC) and hepatic impairment. In addition, the MAH took the opportunity to introduce additional administrative changes and corrections to the PI and Annex II. The RMP version 1.1 has also been submitted.	02/10/2025	07/12/2025	SmPC, Annex II and PL	SmPC new text Clinical PK analysis indicated seladelpar exposures (Cmax, AUC) were 2.1 to 2.5 fold higher in PBC patients with severe hepatic impairment (CP-C) after a single oral dose of 10 mg seladelpar.
Variation type II / EMA/VR/0000280277	This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	04/09/2025	07/12/2025		

	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - 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.e Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product - Accepted				
Variation type IA_IN / EMA/VR/0000287799	This was an application for a group of variations. 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.b Primary packaging site - 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.b Primary packaging site - Accepted	25/07/2025			
Variation type IB / EMA/VR/0000265794	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z – To submit an updated ERA Report to provide Log Dow values within the full pH-range between pH 5 to 9 using the Shake Flask method (OECD 107, OPPTS 830.7550/830.7570).	26/06/2025			

Variation type IB / EMA/VR/0000265714	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	16/05/2025	07/12/2025	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000264096	A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted	14/04/2025	07/12/2025	SmPC, Annex II, Labelling and PL	
Variation type IA_IN / EMA/VR/0000256196	This was an application for a group of variations. 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.a Secondary packaging site - 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.a Secondary packaging site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	24/03/2025	07/12/2025	Annex II and PL	