Rezzayo

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/221/202409	Periodic Safety Update EU Single assessment - rezafungin	10/04/2025	n/a		PRAC Recommendation - maintenance
II/0007	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	27/02/2025		SmPC and PL	As a result of this variation, sections 4.8 and 5.1 of the SmPC are being updated based on final results of China extension part from study ReSTORE.

[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).

					Section 4.8 of the SmPC is being updated to reflect the increase in the safety population and the change in the frequency of the AE anaemia from common to very common. The Package Leaflet (PL) is updated accordingly. Section 5.1 of the SmPC is being updated with the changes in the efficacy results that occurred with the inclusion of the Chinese cohort.
IA/0008/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	19/12/2024	n/a		
PSUSA/221/202403	Periodic Safety Update EU Single assessment - rezafungin	03/10/2024	n/a		PRAC Recommendation - maintenance
II/0002	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	05/09/2024	n/a		
IA/0005	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	26/08/2024	n/a		
IA/0003	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for	30/05/2024	n/a		

	the AS -replacement or addition of a site where batch control/testing takes place				
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	21/02/2024	n/a		