EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Trogarzo

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
IAIN/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/10/2022		SmPC and PL	
PSUSA/10797 /202203	Periodic Safety Update EU Single assessment ibalizumab	29/09/2022	n/a		PRAC Recommendation - maintenance

[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).

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PSUSA/10797 /202109	Periodic Safety Update EU Single assessment - ibalizumab	07/04/2022	n/a		PRAC Recommendation - maintenance
II/0015	Submission of an updated RMP version 2.0 in order to reflect the new timelines of the PROMISE study and to align the information included in the RMP with the latest PSUR. As the PROMISE study is a condition of the Trogarzo marketing authorisation, the delayed start date results in a change to Annex II of the marketing authorisation. The date for providing the final study report is changing from the 31st October 2025 to the 31st October 2026. 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	28/10/2021	19/05/2022	Annex II	
PSUSA/10797 /202103	Periodic Safety Update EU Single assessment - ibalizumab	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0014	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	23/06/2021	19/05/2022	SmPC	
PSUSA/10797 /202009	Periodic Safety Update EU Single assessment - ibalizumab	09/04/2021	n/a		PRAC Recommendation - maintenance

IAIN/0012	A.1 - Administrative change - Change in the name and/or address of the MAH	29/01/2021	19/05/2022	SmPC and PL	
PSUSA/10797 /202003	Periodic Safety Update EU Single assessment - ibalizumab	01/10/2020	n/a		PRAC Recommendation - maintenance
II/0008	B.I.a.4.e - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of an in-process test which may have a significant effect on the overall quality of the AS	03/09/2020	n/a		
IB/0009	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	24/07/2020	n/a		
IA/0007/G	This was an application for a group of variations. 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 B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	12/06/2020	n/a		
IB/0005	B.II.f.1.b.5 - Stability of FP - Extension of the shelf	10/06/2020	21/04/2021	SmPC	

	life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol				
IB/0004	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	13/01/2020	n/a		
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	17/12/2019	21/04/2021	SmPC, Labelling and PL	
IB/0002	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/12/2019	n/a		
IB/0001	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	22/11/2019	n/a		