Alofisel

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
IA/0014	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/01/2020		SmPC, Annex II, Labelling and PL	
IB/0012/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting	19/12/2019	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).

	material/intermediate/reagent - Tightening of specification limits B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0008/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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 B.II.f.1.e - Stability of FP - Change to an approved stability protocol	07/10/2019		SmPC	
PSUSA/10676 /201903	Periodic Safety Update EU Single assessment - darvadstrocel	03/10/2019	n/a		PRAC Recommendation - maintenance
II/0006	Submission of an updated RMP version 7 in order to propose replacement of the observational PASS study (Category 3) with two separate studies: a long-term safety extension of the ADMIRE-CD II study and a retreatment PASS. The European multi-database linkage study is added for the assessment of the potential risk of tumorgenicity. C.I.11.b - Introduction of, or change(s) to, the	29/05/2019	n/a		Following EMA scientific advice this variation was to update the post authorisation follow up on effectiveness and safety as outlined in the RMP in order to more effectively assess long-term effectiveness and safety of darvastocel including repeat administration. The Pharmacovigilance plan was updated and Protocol synopses and on a 4 year extension of the ADMIRE II study, a dedicated re-treatment PASS and a European multi-database linkage study were agreed to

	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				replace the previously agreed re-treatment PASS.
PSUSA/10676 /201809	Periodic Safety Update EU Single assessment - darvadstrocel	11/04/2019	n/a		PRAC Recommendation - maintenance
IB/0005	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	05/04/2019		SmPC, Labelling and PL	
IB/0002	B.II.e.z - Change in container closure system of the Finished Product - Other variation	16/08/2018	n/a		
IAIN/0003/G	This was an application for a group of variations. B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	12/07/2018	n/a		
T/0001	Transfer of Marketing Authorisation	18/04/2018	08/05/2018	SmPC, Labelling and	

				PL	