POTELIGEO

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/0024	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	13/05/2024		SmPC, Annex II, Labelling and PL	

[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).

IB/0023	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	16/01/2024	n/a		
PSUSA/10741 /202303	Periodic Safety Update EU Single assessment - mogamulizumab	26/10/2023	n/a		PRAC Recommendation - maintenance
R/0021	Renewal of the marketing authorisation.	22/06/2023	01/09/2023	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of POTELIGEO in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0020	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	31/08/2023	n/a		
II/0019/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	26/04/2023	n/a		
II/0018	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	26/04/2023	n/a		
PSUSA/10741 /202203	Periodic Safety Update EU Single assessment - mogamulizumab	27/10/2022	n/a		PRAC Recommendation - maintenance

PSUSA/10741 /202109	Periodic Safety Update EU Single assessment - mogamulizumab	05/05/2022	n/a		PRAC Recommendation - maintenance
IA/0016	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/04/2022	24/04/2023	SmPC	
II/0013/G	This was an application for a group of variations. B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS	17/02/2022	n/a		
IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	13/12/2021	29/04/2022	Annex II and PL	
PSUSA/10741 /202103	Periodic Safety Update EU Single assessment - mogamulizumab	28/10/2021	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	23/06/2021	29/04/2022	SmPC and PL	
PSUSA/10741 /202009	Periodic Safety Update EU Single assessment - mogamulizumab	06/05/2021	n/a		PRAC Recommendation - maintenance

II/0010/G	This was an application for a group of variations. Update section 4.8 of the SmPC with the submission of data from Study 0761-010 for ADA based on the revised assay as requested by the CHMP in order to review the revised data, and a reanalysis of the effect of ADA on safety, efficacy and mogamulizumab PK of subjects previously considered "inconclusive" now resulting in ADA positive. Update of section 4.6 to remove the statement on contraception requirements for male subjects/patients from the product information. The PL is updated accordingly. The MAH took the opportunity to update the PI in accordance with the QRD template v10.1. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/03/2021	29/04/2022	SmPC, Annex II and PL	The information on anti-drug antibodies in section 4.8 of the SmPC was updated with the submission of data from Study 0761-010 for ADA based on the revised assay as requested by the CHMP. Following the review of the revised data, and a reanalysis of the effect of ADA on safety, efficacy and mogamulizumab PK of subjects previously considered "inconclusive" now resulting in ADA positive. Therefore it is now reflected in the SmPC that following infusion of POTELIGEO during clinical studies of the use of POTELIGEO in patients with adult T-cell leukaemia-lymphoma or cutaneous T-cell lymphoma, approximately 14% of patients (44 out of 313 evaluable patients) tested positive for treatment emergent anti-mogamulizumab antibodies. There were no patients identified to have positive neutralising antibody responses. Based on the available non-clinical reproductive and developmental toxicity data for mogamulizumab, section 4.6 was updated to remove the statement on contraception requirements for male subjects/patients from the product information. The PL is updated accordingly. The MAH took the opportunity to update the PI in accordance with the QRD template v10.1.
II/0008	B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	14/01/2021	n/a		
IB/0007	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition	09/11/2020	n/a		

	of a new in-process test and limits				
PSUSA/10741 /202003	Periodic Safety Update EU Single assessment - mogamulizumab	29/10/2020	n/a		PRAC Recommendation - maintenance
II/0005/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	23/07/2020	n/a		
PSUSA/10741 /201909	Periodic Safety Update EU Single assessment - mogamulizumab	17/04/2020	n/a		PRAC Recommendation - maintenance
IAIN/0003/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 A.5.b - Administrative change - Change in the name	06/11/2019	19/10/2020	Annex II and PL	

	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10741 /201903	Periodic Safety Update EU Single assessment - mogamulizumab	31/10/2019	n/a		PRAC Recommendation - maintenance
IB/0002	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	26/07/2019	n/a		