Besremi

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
R/0031	Renewal of the marketing authorisation.	12/10/2023	07/12/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Besremi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

PSUSA/10756 /202302	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	28/09/2023	n/a		PRAC Recommendation - maintenance
II/0026	B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	19/01/2023	n/a		
IB/0029	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	06/12/2022	07/12/2023	SmPC	
II/0025	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	01/12/2022	n/a		
IB/0027	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	23/11/2022	n/a		
II/0021	Update of sections 4.8, 5.1 and 5.2 of the SmPC based on results from CONTINUATION-PV study. An open-label, multicentre, phase IIIb study assessing	17/11/2022	07/12/2023	SmPC and PL	Not applicable.

	the long-term efficacy and safety of AOP2014 and standard first line treatment (BAT) in patients with polycythaemia vera who previously participated in the PROUDPV Study. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IA/0028	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	26/10/2022	n/a		
PSUSA/10756 /202202	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	29/09/2022	n/a		PRAC Recommendation - maintenance
IA/0024	B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	11/05/2022	n/a		
IB/0022	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	19/04/2022	n/a		
IB/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/01/2022	n/a		

IAIN/0019	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	01/10/2021	31/01/2022	Annex II and PL	
PSUSA/10756 /202102	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	30/09/2021	n/a		PRAC Recommendation - maintenance
IAIN/0018/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.1 - Administrative change - Change in the name and/or address of the MAH	20/09/2021	31/01/2022	SmPC, Labelling and PL	
IB/0017	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	13/09/2021	n/a		
IB/0016/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	16/07/2021	n/a		

IB/0013	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/06/2021	n/a		
IA/0014	B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised	27/04/2021	n/a		
PSUSA/10756 /202008	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	11/03/2021	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	13/01/2021	31/01/2022	SmPC, Labelling and PL	
IB/0012	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	18/12/2020	n/a		
IA/0009/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	31/10/2020	n/a		

PSUSA/10756 /202002	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	01/10/2020	n/a		PRAC Recommendation - maintenance
IA/0008	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/09/2020	n/a		
II/0006/G	This was an application for a group of variations. 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 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 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	25/06/2020	n/a		
IB/0005	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	23/03/2020	n/a		
PSUSA/10756 /201908	Periodic Safety Update EU Single assessment - ropeginterferon alfa-2b	12/03/2020	n/a		PRAC Recommendation - maintenance

IA/0004	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	07/02/2020	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/12/2019	31/01/2022	Labelling	
IB/0001/G	This was an application for a group of variations. 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 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	08/07/2019	n/a		