Pepaxti

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/11013 /202308	Periodic Safety Update EU Single assessment - melphalan flufenamide	07/03/2024	n/a		PRAC Recommendation - maintenance
IA/0011	B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	29/02/2024	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).

IA/0010	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	09/02/2024	n/a		
IB/0008	C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication	01/02/2024	01/03/2024	SmPC and PL	
IB/0009	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	30/01/2024	n/a		
II/0002	Extension of indication to include treatment of patients with Multiple Myeloma who have received at least two prior lines of therapies for PEPAXTI, based on final results from study OP-103 OCEAN; this is a randomized, open-label phase III study in patients with relapsed or refractory multiple myeloma following two to four lines of prior therapies and who were refractory to lenalidomide and the last line of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/09/2023	14/12/2023	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Pepaxti-H-C-5681-II-0002'

IB/0006	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	12/12/2023	n/a		
IAIN/0007	A.1 - Administrative change - Change in the name and/or address of the MAH	27/11/2023	01/03/2024	SmPC, Labelling and PL	
IB/0004	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/11/2023	01/03/2024	SmPC	
PSUSA/11013 /202302	Periodic Safety Update EU Single assessment - melphalan flufenamide	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	19/12/2022	14/12/2023	SmPC	