KIMMTRAK

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/10991 /202401	Periodic Safety Update EU Single assessment - tebentafusp	19/09/2024	14/11/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10991/202401.
II/0007	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	17/10/2024	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).

II/0005	Update of section 5.1 of the SmPC in order to include the updated Overall Survival (OS) data based on results from study IMCgp100-202; this is a phase III randomized, open-label, multi-center study of the safety and efficacy of IMCgp100 compared with investigator's choice in HLA-A*0201 positive patients with previously untreated advanced uveal melanoma. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/06/2024	14/11/2024	SmPC	SmPC new text Section 5.1 of the SmPC is updated to include updated overall survival data based on an analysis with 3 years of follow-up. At the time of this analysis 16 patients from the control group have crossed-over to the tebentafusp treatment. After 3 years of follow-up, tebentafusp continues to provide a substantial survival benefit compared with investigator's choice. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10991 /202307	Periodic Safety Update EU Single assessment - tebentafusp	08/02/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10991 /202303	Periodic Safety Update EU Single assessment - tebentafusp	26/10/2023	n/a		PRAC Recommendation - maintenance
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/10/2023	14/11/2024	PL	
PSUSA/10991 /202209	Periodic Safety Update EU Single assessment - tebentafusp	14/04/2023	n/a		PRAC Recommendation - maintenance