Copiktra

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
IB/0007/G	This was an application for a group of variations. 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) B.II.f.1.e - Stability of FP - Change to an approved	10/08/2023		SmPC	

[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).

	stability protocol				
IA/0008	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	13/07/2023	n/a		
PSUSA/10939 /202209	Periodic Safety Update EU Single assessment - duvelisib	14/04/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10939 /202203	Periodic Safety Update EU Single assessment - duvelisib	27/10/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10939 /202109	Periodic Safety Update EU Single assessment - duvelisib	07/04/2022	n/a		PRAC Recommendation - maintenance
II/0002	Update of section 5.1 of the SmPC based on the final overall survival results from Study IPI-145-07, an interventinal Phase 3 Study of duvelisib (IPI-145) vs ofatumumab in patients with relapsed or refractory Chronic Lymphocytic leukemia/Small Lymphocytic Lymphoma. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	27/01/2022	03/02/2023	SmPC	For more information, please refer to the Summary of Product Characteristics.
T/0001	Transfer of Marketing Authorisation	16/07/2021	20/08/2021	SmPC, Labelling and PL	