Adakveo

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/10888 /202205	Periodic Safety Update EU Single assessment - crizanlizumab	01/12/2022	n/a		PRAC Recommendation - maintenance
IB/0010/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits	06/10/2022	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).

	applied during the manufacture of the AS - Tightening of in-process limits B.I.e.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol				
II/0007	Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on the results from PK re-analysis. In addition, the MAH took the opportunity to introduce minor editorial changes to the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/09/2022		SmPC	Update of section 5.2 of the SmPC to include information from PK reanalysis. For more information, please refer to the Summary of Product Characteristics.
R/0008	Renewal of the marketing authorisation.	23/06/2022	12/08/2022		
PSUSA/10888 /202111	Periodic Safety Update EU Single assessment - crizanlizumab	10/06/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10888 /202105	Periodic Safety Update EU Single assessment - crizanlizumab	02/12/2021	n/a		PRAC Recommendation - maintenance
II/0005	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	21/10/2021	n/a		
R/0003	Renewal of the marketing authorisation.	22/07/2021	29/09/2021		
PSUSA/10888 /202011	Periodic Safety Update EU Single assessment - crizanlizumab	24/06/2021	26/08/2021	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/10888/202011.
IB/0002/G	This was an application for a group of variations. 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 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	11/06/2021	26/08/2021	SmPC and PL	