Regkirona

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/0021	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/10/2024	n/a		
PSUSA/10964 /202402	Periodic Safety Update EU Single assessment - regdanvimab (Regkirona)	05/09/2024	n/a		PRAC Recommendation - maintenance

[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).

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PSUSA/10964 /202308	Periodic Safety Update EU Single assessment - regdanvimab (Regkirona)	07/03/2024	n/a		PRAC Recommendation - maintenance
IB/0019	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	26/02/2024	n/a		
PSUSA/10964 /202302	Periodic Safety Update EU Single assessment - regdanvimab (Regkirona)	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0016	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	24/08/2023	10/10/2023	SmPC	
IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	04/05/2023	n/a		
IB/0012/G	This was an application for a group of variations: B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	24/04/2023	n/a		
IA/0013	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	31/03/2023	10/10/2023	SmPC	
PSUSA/10964 /202208	Periodic Safety Update EU Single assessment - regdanvimab (Regkirona)	16/03/2023	n/a		PRAC Recommendation - maintenance

IB/0010	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	12/12/2022	10/10/2023	SmPC	
II/0008	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	10/11/2022	10/10/2023	SmPC	
IB/0009	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	27/10/2022	n/a		
II/0005	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/10/2022	n/a		
PSUSA/10964 /202202	Periodic Safety Update EU Single assessment - regdanvimab (Regkirona)	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0007	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	21/07/2022	10/10/2023	SmPC, Labelling and PL	To update the product information as follows: - To update Section 6.3 of the SmPC to extend the shelf-life of the finished product from 18 months to 21 months. - To introduce editorial changes including deletion of the QR code from Annex III (Labelling, section 18 and Package Leaflet, section 6) and to implement linguistic review comments from the German and Hungarian health authorities.
II/0004	Update of section 5.1 of the SmPC to include in vitro	19/05/2022	25/05/2022	SmPC	In vitro data suggest that the SARS-CoV-2 B.1.1.529

	neutralization activity of regdanvimab against the SARS-CoV-2 B.1.1.529 (Omicron) variant of concern based on report REP-ND22-047. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				(Omicron) variant shows reduced susceptibility against regdanvimab (Regkirona).
IB/0003/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.II.f.1.e - Stability of FP - Change to an approved stability protocol	13/04/2022	25/05/2022	SmPC	
II/0002	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	24/03/2022	n/a		
IB/0001	To extend the shelf-life of the finished product from 1 year to 15 months when stored at 2°C to 8°C. 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	13/12/2021	25/05/2022	SmPC, Annex II and PL	To extend the shelf-life of the finished product from 1 year to 15 months when stored at 2°C to 8°C.