EVKEEZA

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
II/0015	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/11/2024	13/12/2024	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Evkeeza-H-C-005449-II-0015'
IB/0020	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	27/11/2024	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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000

S/0018	Annual re-assessment.	19/09/2024	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of EVKEEZA should be maintained.
PSUSA/10945 /202402	Periodic Safety Update EU Single assessment - evinacumab	05/09/2024	n/a		PRAC Recommendation - maintenance
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/07/2024	13/12/2024	PL	
IAIN/0017/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	04/06/2024	n/a		
PSUSA/10945 /202308	Periodic Safety Update EU Single assessment - evinacumab	07/03/2024	n/a		PRAC Recommendation - maintenance

II/0011	Extension of indication to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia (HoFH) aged 5 years and older for EVKEEZA, based on interim results from study R1500-CL-17100, as well as supportive information from an updated interim analysis of study R1500-CL-1719, and an extrapolation analysis (including population PK, population PK/PD, and simulation analyses). R1500-CL-17100 is an ongoing multicentre, three-part, single-arm, open-label study evaluating the efficacy, safety, and tolerability of evinacumab in paediatric patients aged ≥ 5 to 11 years with HoFH. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the marketing authorisation holder took the opportunity to introduce minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.3. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	09/11/2023	11/12/2023	SmPC, Annex II and PL	Please refer to Scientific Discussion 'EMEA-H-C-005449-II-0011'
IB/0014	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	30/11/2023	n/a		

IB/0012/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	09/11/2023	n/a		
PSUSA/10945 /202302	Periodic Safety Update EU Single assessment - evinacumab	28/09/2023	n/a		PRAC Recommendation - maintenance
S/0010	Annual re-assessment.	14/09/2023	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of EVKEEZA should be maintained.
IB/0009	B.II.h.1.b.2 - Update to the Adventitious Agents Safety Evaluation information - Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - without modifications of risk assessment	15/06/2023	n/a		
PSUSA/10945 /202208	Periodic Safety Update EU Single assessment - evinacumab	16/03/2023	n/a		PRAC Recommendation - maintenance
IAIN/0006/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/10/2022	05/10/2023	SmPC, Annex II and PL	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10945 /202202	Periodic Safety Update EU Single assessment - evinacumab	29/09/2022	n/a		PRAC Recommendation - maintenance
S/0005	1st annual re-assessment	15/09/2022	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of EVKEEZA should be maintained.
T/0003	Transfer of Marketing Authorisation	31/03/2022	13/04/2022	SmPC, Labelling and PL	

IB/0002/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.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 B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	11/04/2022	n/a		
PSUSA/10945 /202108	Periodic Safety Update EU Single assessment - evinacumab	10/03/2022	n/a		PRAC Recommendation - maintenance