Vabysmo

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/0016	Update of section 5.1 of the Summary of Product Characteristics (SmPC) to reflect the long-term safety profile of faricimab in patients with diabetic macular oedema (DME) based on the final results from study GR41987 (Rhone-X), listed as category 3 study in the Risk Management Plan (RMP). Rhone-X	08/05/2025		SmPC and PL	Update of SmPC section 5.1 to reflect the long-term safety profile and tolerability of faricimab in patients with diabetic macular oedema based on the final results from (category 3) study GR41987 (Rhone-X). In addition, SmPC section 4.4 (and PL, accordingly) was updated to highlight information about educational material (a guide to ensure

[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).

	was a phase III interventional, multicentre, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with DME. In addition, SmPC section 4.4 and the package leaflet (PL) were updated to highlight information about the educational material (a guide to ensure awareness of signs and symptoms of intraocular inflammation and endophthalmitis and actions to take) provided to the patient / career by the prescriber. The MAH took also the opportunity to introduce other minor (administrative) changes, in both SmPC and PL. The RMP version 7.1 was also approved. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				awareness of signs and symptoms of intraocular inflammation and endophthalmitis and actions to take) provided to the patient / career by the prescriber.
PSUSA/11016 /202407	Periodic Safety Update EU Single assessment - faricimab	13/02/2025	n/a		PRAC Recommendation - maintenance
II/0014	Update of section 4.2 of the SmPC to modify the posology for two approved indications, neovascular (wet) Age-related Macular Degeneration (nAMD) and visual impairment due to Diabetic Macular Edema (DME), based on the post-hoc efficacy analysis of Phase III interventional nAMD studies TENAYA (GR40306) and LUCERNE (GR40844), and Phase III interventional DME studies YOSEMITE (GR40349) and RHINE (GR40398). The Package Leaflet is updated accordingly.	14/11/2024	19/12/2024	SmPC and PL	Update of section 4.2 of the SmPC to modify the posology for two approved indications, neovascular (wet) Age-related Macular Degeneration (nAMD) and visual impairment due to Diabetic Macular Edema (DME), based on the post-hoc efficacy analyses of Phase III interventional studies. The PL is updated accordingly. For more information, please refer to the Summary of Product Characteristics.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IA/0017	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	16/12/2024	n/a		
II/0011/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	12/12/2024		SmPC, Annex II, Labelling and PL	The SmPC section 1, 2, 3, 4.2, 4.4, 6.3, 6.4, 6.5, 6.6, and 8 has been updated to reflect the introduction of the prefilled syringe, co-packaged with a CE-marked injection filter needle [EU/1/22/1683/002] specific information. The Labelling and PL have been updated accordingly.

	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products				
IA/0018/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	11/12/2024	n/a		
IB/0013	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		To extend the due date of 3 studies in the RMP.

PSUSA/11016 /202401	Periodic Safety Update EU Single assessment - faricimab	05/09/2024	n/a		PRAC Recommendation - maintenance
II/0005	Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemi-retinal vein occlusion (HRVO). These are global, multicentre, randomised, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	27/06/2024	26/07/2024	SmPC, Annex II and PL	Please refer to the Scientific Discussion.
IB/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	03/07/2024	n/a		

II/0009	Update of section 4.8 of the SmPC in order to add 'Retinal Vasculitis' and 'Retinal Occlusive Vasculitis' to the list of adverse drug reactions (ADRs) with frequency not known, based on a drug safety report and post-marketing data; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to add study CR45271 as a category 3 study in the RMP, to introduce minor changes and corrections to the PI and to update the list of local representatives in the Package Leaflet C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/02/2024	20/06/2024	SmPC and PL	Not applicable
PSUSA/11016 /202307	Periodic Safety Update EU Single assessment - faricimab	08/02/2024	n/a		PRAC Recommendation - maintenance
IA/0007/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits 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	21/09/2023	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - 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 B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and 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				
PSUSA/11016 /202301	Periodic Safety Update EU Single assessment - faricimab	31/08/2023	n/a		PRAC Recommendation - maintenance
IA/0006	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	01/08/2023	n/a		
II/0002	Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information and to update the warnings and the list of adverse drug reactions (ADRs), based on longer-term results	22/06/2023	20/06/2024	SmPC and PL	The SmPC has been updated in line with the safety and efficacy data from long-term studies. The posology for neovascular age related macular degeneration, adverse events frequency and section 5.1 are updated in line with

	from studies GR40306 (TENAYA) and GR40844 (LUCERNE); these are phase 3, multicenter, randomized, double-masked, active comparator-controlled, 112-week studies to evaluate the efficacy and safety of faricimab in patients with neovascular age-related macular degeneration (nAMD); the Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				the long-term treatment study findings. The proposed changes can be agreed if there are satisfactory responses to the list of issues and supplementary information requested.
IB/0003	B.I.b.z - Change in control of the AS - Other variation	04/04/2023	n/a		
IB/0001	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/11/2022	n/a		