Columvi

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/0010	Submission of the updated 2-year follow-up report from study NP30179 listed as a Specific Obligation in the Annex II of the Product Information. This is a multicenter, open-label Phase I/II study to evaluate the safety, efficacy, tolerability, and pharmacokinetics of escalating doses of glofitamab in	27/02/2025	08/05/2025	Annex II	Not applicable.

[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).

	patients with relapsed/refractory B-cell Non-Hodgkin's Lymphoma (NHL). The Annex II is updated accordingly. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. An editorial update in section 5.1 of the SmPC is made as the statement on CMA is removed. The PL is updated accordingly. The RMP version 5.0 was submitted. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/67/202409	Periodic Safety Update EU Single assessment - glofitamab	10/04/2025	n/a		PRAC Recommendation - maintenance
II/0005	Extension of indication to include in combination with gemcitabine and oxaliplatin the treatment of adult patients with relapse or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) for COLUMVI, based on results of primary and updated analyses from study GO41944 (STARGLO) listed as a Specific Obligation in the Annex II of the Product Information, as well supportive data from the Phase Ib study GO41943. Study GO41944 (STARGLO) is a Phase III, open-label, multicenter, randomised study of glofitamab in combination with GemOx (Glofit-GemOx) vs.	27/02/2025	10/04/2025	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Product Name-H-C-Product Number-II-Var.No'

	rituximab in combination with GemOx (R-GemOx) in patients with R/R DLBCL. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/01/2025	n/a		
IB/0008	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/12/2024	10/04/2025	SmPC, Annex II and PL	
II/0006/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting	07/11/2024	n/a		

	material/intermediate 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.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				

PSUSA/67/202403	Periodic Safety Update EU Single assessment - glofitamab	31/10/2024	n/a		PRAC Recommendation - maintenance
R/0003	Renewal of the marketing authorisation.	21/03/2024	27/05/2024		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Columvi, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/67/202309	Periodic Safety Update EU Single assessment - glofitamab	11/04/2024	n/a		PRAC Recommendation - maintenance
IB/0001	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	03/01/2024	27/05/2024	SmPC and PL	