MINJUVI

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification[1] issued	Commission Decision Issued[2] /	Product Information affected[3]	Summary

[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).

						on	amended on	
Variation type IB / EMA/VR/0000310661					This was an application for a group of variations. B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	18/12/2025	15/12/2025	SmPC
Variation type IA / EMA/VR/0000317412	This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the	12/12/2025	N/A					

	manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Variation type IA / EMA/VR/0000309782	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	27/11/2025	N/A		
Variation type II / EMA/VR/0000255975	C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new	13/11/2025	15/12/2025	SmPC and PL	

	therapeutic indication or modification of an approved one - Accepted Extension of indication to include in combination with lenalidomide and rituximab treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least one line of systemic therapy for MINJUVI, based on interim results from study INCMOR 0208-301 (inMIND); this is a phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of tafasitamab plus lenalidomide and rituximab vs lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma grade 1 to 3a or R/R marginal zone lymphoma. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated				

	in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.				
Variation type II / EMA/VR/0000269625	This was an application for a group of variations. B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.c Change to an approved	30/10/2025	15/12/2025	Annex II	

	stability protocol - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to				

	an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance -				

	B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.c The change requires assessment of the comparability of a biological/immunological medicinal product or the change in batch size requires a new bioequivalence study - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the				

	manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted				
Variation type IB / EMA/VR/0000302636	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z - to update Annex II.E of the Product	24/10/2025	15/12/2025	Annex II	

	Information and the RMP to change the due date for the Specific Obligation MOR208C310 (frontMIND), from 'December 2025' to 'December 2026'.				
Renewal - 1 year / EMA/R/0000256675	- Renewal - Accepted	24/07/2025	17/09/2025	Annex II	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 MINJUVI, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. The SOB relating to the B-MIND study is fulfilled and therefore deleted from the SmPC. In addition, the SOB relating to the frontMIND study has been amended and is included in its updated form in the SmPC: "In order to confirm the efficacy and to re-confirm the safety profile of tafasitamab in combination with lenalidomide the applicant should submit the results of a phase 3, multicentre, randomized, double-blind, placebo-controlled trial comparing tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL)".
Variation type IB / EMA/VR/0000261395	This was an application for a group of variations. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters	03/04/2025	N/A		

	and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted				
Variation type IB / EMA/VR/0000244988	This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.c Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermedia	12/02/2025	N/A		

	te used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Minor change of an analytical procedure for an in-process control - Accepted								
PSUR / EMA/PSUR/0000269001					- -				Maintenance