Korjuny

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 on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	19/03/2026		SmPC	EpCAM expression in the clinical studies was

[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).

EMA/VR/0000304947	PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted Submission of the final report from study concerning the validation of quantification of EpCAM-positive cells in malignant ascites samples for EpCAM CytoDetect Assay implementation using HO-3 primary anti-body to fulfil commitment given during the Marketing Authorisation Application (EMEA/H/C/005697).				determined using a validated immunocytochemical assay applied to malignant ascites samples, with a positivity threshold of ≥ 400 EpCAM-positive cells per 10^6 analysed ascites cells. Where a CE-marked in vitro diagnostic device with the appropriate intended purpose is not available, alternative assays used in clinical practice should be validated and demonstrate appropriate analytical performance characteristics for this intended use. For more information, please refer to the Summary of Product Characteristics.
Variation type IA_IN / EMA/VR/0000297256	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	23/09/2025		Annex II and PL	
Variation type IA_IN / EMA/VR/0000287504	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	30/07/2025			
Variation type IB / EMA/VR/0000281784	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted	15/07/2025			
Variation type IB / EMA/VR/0000278207	This was an application for a group of variations.	26/06/2025			

	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted				
Variation type IB / EMA/VR/0000276239	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.z Other changes - Accepted	23/06/2025			
Variation type IB / EMA/VR/0000276206	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	23/06/2025		SmPC	
Marketing Authorisation Transfer - H / EMA/T/0000258313	transfer of marketing authorisation from Lindis Biotech GmbH to Atnahs Pharma Netherlands B.V.	28/03/2025	15/05/2025	SmPC, Labelling and PL	

Variation type IA_IN / EMA/VR/0000255947	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.12 Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring - Accepted	26/03/2025	15/05/2025	SmPC and PL	To include in the Product Information the black symbol and explanatory statement for medicinal products that are subject to additional monitoring.
PSUR / EMA/PSUR/0000311171					Maintenance