Tecartus

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 / EMA/VR/0000308229	Outcome: This was an application for a variation following a worksharing procedure according	23/04/2026		SmPC, Annex II and PL	The SmPC was updated to include the following new text: 'After the first 7 days following the infusion, the patient is to be monitored at the physician's

[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).

	to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.4, 4.5. 4.7 and 6.4 of the SmPC in order to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS (cytokine release syndrome) and ICANS (immune effector cell-associated neurotoxicity syndrome) based on data from clinical trials, post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 8.0 for Tecartus and RMP version 13.0 for Yescarta have also been submitted. In addition, Annex II has been updated accordingly. Furthermore, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the PI.				discretion for at least an additional 7 days.' 'Patients must remain within proximity of a qualified treatment centre or appropriately trained clinical facility for at least 2 weeks following infusion'. 'patients must refrain from driving or operating heavy or potentially dangerous machines for a minimum of 4 weeks after infusion or until complete resolution of neurologic adverse reactions. 'Prophylactic use of systemic corticosteroids is not routinely recommended (see section 4.5). Prophylactic use of systemic corticosteroids may be considered in patients at increased risk of severe immune-mediated adverse reactions, if the potential benefit outweighs the risk and as guided by local institutional and/or national or European/international guidelines.' For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000338844	Outcome: Q.I.b.2 Change to analytical procedure for	17/04/2026			

	active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.b) Deletion of an analytical procedure for the active substance if an alternative procedure is already authorised - Accepted Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.b) Deletion of an analytical procedure for the active substance if an alternative procedure is already authorised - Accepted Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.b) Deletion of an analytical procedure for the active substance if an alternative procedure is already authorised - Accepted				
PSUR / EMA/PSUR/0000305034	EURD: PSUSA/00010903/202507 Active substance: brexucabtagene autoleucel Outcome: Variation In view of available data on secondary malignancy of myeloid origin from clinical	26/02/2026	04/05/2026	SmPC and PL	Variation

	trial(s), the literature, and spontaneous reports including cases with a fatal outcome, the PRAC considers that a warning on secondary malignancy of myeloid origin is warranted. The PRAC concluded that the product information of products containing brexucabtagene autoleucel should be amended accordingly.				
Variation type II / EMA/VR/0000309793	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted	26/02/2026	04/05/2026	SmPC, Labelling and PL	The SmPC section 6.4 has been updated as follows: Yescarta/Tecartus must be stored at ≤ -120 °C and must remain frozen until the patient is ready for treatment to ensure viable live autologous cells are available for patient administration. The Labelling and PL have been updated accordingly.
Variation type II / EMA/VR/0000280312	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c	11/12/2025			Not applicable

	The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative and/or quantitative composition - 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 Other variation - Accepted				
Variation type II / EMA/VR/0000285857	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.4 of the SmPC in order to add a reference statement to current	13/11/2025	04/05/2026	SmPC and Annex II	Not applicable

	institutional / national guidelines for the monitoring and management of CRS, neurologic events and ICANS. In addition, the MAH took the opportunity to introduce clarification and administrative updates across the PI, including Annex II.				
PSUR / EMA/PSUR/0000268989	EURD: PSUSA/00010903/202501 Active substance: brexucabtagene autoleucel Outcome: Variation In view of available data on status epilepticus from clinical trials, spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between brexucabtagene autoleucel and status epilepticus is at least a reasonable possibility. The PRAC concluded that the product information of products containing brexucabtagene autoleucel should be amended accordingly.	18/09/2025	17/11/2025	SmPC and PL	Variation
Renewal - 1 year / EMA/R/0000278705	Outcome: - Renewal - Accepted Renewal of marketing authorisation	18/09/2025	17/11/2025		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 Tecartus, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
Variation type II / EMA/VR/0000255932	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted	24/07/2025	17/11/2025	SmPC, Labelling and PL	The SmPC section 6.4 has been updated as follows: Yescarta/Tecartus may be stored a single time at -80 °C (± 10 °C), for up to 90 days. After storage at -80 °C (± 10 °C), the product must be used within the 90-day period or the labelled expiration date, whichever comes first. After these dates, the product must not be used and must be discarded. The Labelling and Package Leaflet have been updated accordingly.
Variation type IB / EMA/VR/0000265127	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate	12/06/2025			

	used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted				
Variation type II / EMA/VR/0000257524	Outcome: 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.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted Submission of the 57-month follow-up results from study ZUMA-3 (KTE-C19-103) listed as a Specific Obligation in the Annex II of the Product Information. This is a phase 1/2 open-label study evaluating the safety and efficacy of brexucabtagene autoleucel in adult participants with relapsed/refractory B-	22/05/2025	17/11/2025	Annex II	The results of the 57-month analysis are consistent with the results reported in the Primary Analysis clinical study report (CSR) and the prior CSR addenda. No new safety signals were identified. The benefit-risk balance of Tecartus remains positive.

	precursor acute lymphoblastic leukemia (r/r ALL). The Annex II is updated accordingly.				
Variation type II / EMA/VR/0000242383	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.d Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted - - Accepted	27/03/2025			Not applicable