Tecartus

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
WS/2821/G	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.1.j - Change in the manufacturer of AS or of a	27/03/2025	n/a		

[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).

	starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB				
WS/2736	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.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	27/02/2025	n/a		
R/0047	Renewal of the marketing authorisation.	12/12/2024	26/02/2025	SmPC	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.
PSUSA/10903 /202407	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	13/02/2025	n/a		PRAC Recommendation - maintenance

WS/2813/G	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.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	16/01/2025	n/a		
WS/2500	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	12/12/2024	n/a		
IB/0050/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.1.z - Change in the manufacturer of AS or of a	09/12/2024	n/a		

	starting material/reagent/intermediate for AS - Other variation				
WS/2689	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.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	19/09/2024	n/a		
PSUSA/10903 /202401	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	05/09/2024	n/a		PRAC Recommendation - maintenance
IG/1781	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/08/2024	26/02/2025	SmPC, Annex II and PL	
WS/2613	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/07/2024	n/a		
IB/0044	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/05/2024	26/02/2025	Annex II	

WS/2632	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.2 of the SmPC in order to update the safety monitoring timelines based on data from clinical studies, postmarketing studies, and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to other sections of the SmPC to align the language across both products. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/04/2024	26/02/2025	SmPC and PL	Based on accumulated data for Tecartus and Yescarta, the SmPCs for both products are updated to indicate that the daily monitoring for signs and symptoms of potential CRS, neurologic events, and other toxicities can be reduced from 10 to 7 days following CAR T cell infusion. For more information, please refer to the Summary of Product Characteristics.
WS/2607	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.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	25/04/2024	n/a		
PSUSA/10903 /202307	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	22/02/2024	19/04/2024	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10903/202307.

WS/2646	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.z - Quality change - Finished product - Other variation	04/04/2024	n/a		
R/0034	Renewal of the marketing authorisation.	12/10/2023	07/12/2023	SmPC and Annex II	The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, are 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.
PSUSA/10903 /202301	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	14/09/2023	15/11/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10903/202301.
IB/0038	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	03/11/2023	n/a		
WS/2558/G	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.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	05/10/2023	n/a		

	B.I.b.1.i - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Where there is no monograph in the European/National Ph. for the AS, a change in specification from in-house to a non-official/third country Ph.				
IB/0035	B.I.b.z - Change in control of the AS - Other variation	28/09/2023	n/a		
WS/2389/G	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.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	25/05/2023	n/a		
WS/2426	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.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	30/03/2023	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
PSUSA/10903 /202207	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	09/02/2023	n/a		PRAC Recommendation - maintenance
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/01/2023	09/10/2023	Labelling	
R/0025	Renewal of the marketing authorisation.	15/09/2022	15/11/2022		The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, are 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 Obligation and Conditions as laid down in Annex II to the opinion.
IB/0026	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	21/09/2022	09/10/2023	Annex II	
WS/2247	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.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates,	15/09/2022	n/a		

	which may have a significant effect on the quality of the AS and/or the FP				
II/0008/G	This was an application for a group of variations. Group of variations including and extension of indication to include treatment of adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) for Tecartus and a type IB variation to change the Drug Product Dose specification for the new indication. As a consequence, sections 2.2, 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. Annex II is updated to reflect the new Specific Obligations for the new indication. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	21/07/2022	02/09/2022	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Product Name-H-C-Product Number-II-Var.No'
PSUSA/10903 /202201	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0028	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	23/08/2022	n/a		

IB/0027	B.I.b.z - Change in control of the AS - Other variation	09/08/2022	n/a		
WS/2269	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	23/06/2022	n/a		
II/0019	Update of sections 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on 24-month follow-up data from all treated patients in cohort 1 of the pivotal clinical study, KTE-C19-102 (ZUMA-2); a Phase 2, multicenter, open-label study evaluating the safety and efficacy of KTE-X19 in subjects with relapsed or refractory (r/r) mantle cell lymphoma (MCL). This submission is in fulfilment of the specific obligation (SOB 004) to confirm the long-term efficacy and safety of Tecartus in adult patients with relapsed/refractory (r/r) MCL. As a consequence Annex II E has been updated with deletion of the fulfilled SOB. In addition, the MAH has taken the opportunity to make minor editorial changes in the SmPC. The RMP version 2.1 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/06/2022	02/09/2022	SmPC and Annex II	The updated 24-month follow-up analyses of efficacy were conducted using the modified intent to treat (mITT) analysis set, which consisted of 68 patients treated with Tecartus. In the 24-month follow up analysis, the ORR and CR rates in the 68 patients in the mITT analysis set were 91% and 68% respectively. For more information, please refer to the Summary of Product Characteristics.
IB/0024	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other	25/05/2022	n/a		

	variation				
WS/2194	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	22/04/2022	n/a		
IAIN/0023	A.3 - Administrative change - Change in name of the AS or of an excipient	21/04/2022	02/09/2022	SmPC, Labelling and PL	
II/0016	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	24/03/2022	n/a		
WS/2197	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	24/02/2022	n/a		
PSUSA/10903 /202107	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	10/02/2022	n/a		PRAC Recommendation - maintenance
WS/2181	This was an application for a variation following a worksharing procedure according to Article 20 of	27/01/2022	n/a		

	Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
WS/2206	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.2 and 4.4 of the SmPC and Annex IID in order to add statements for the use of Tecartus and Yescarta exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab". The RMPs for both products are updated accordingly (version 1.2 for Tecartus and version 5.2 for Yescarta). The update of the RMPs for both products (version 1.2 for Tecartus and version 5.2 for Yescarta) C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/12/2021	24/01/2022	SmPC, Annex II and PL	The product information has been amended to reflect that in the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, suitable alternative measures to treat CRS instead of tocilizumab should be available on-site. For more information, please refer to the Summary of Product Characteristics.
II/0012	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	16/12/2021	n/a		

R/0010	Renewal of the marketing authorisation.	16/09/2021	18/11/2021		The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, are 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.
N/0011	Transfer of Marketing Authorisation	17/09/2021	24/01/2022	PL	
WS/2071	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.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	16/09/2021	n/a		
PSUSA/10903 /202101	Periodic Safety Update EU Single assessment - brexucabtagene autoleucel	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0009	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	06/07/2021	n/a		
IB/0005/G	This was an application for a group of variations.	12/05/2021	n/a		

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB				
IB/0003	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	23/04/2021	n/a		
II/0001	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	22/04/2021	n/a		
IB/0004	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	31/03/2021	n/a		
IB/0002	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	09/03/2021	n/a		