Tecvayli

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
PSUSA/11010 /202408	Periodic Safety Update EU Single assessment - teclistamab	13/03/2025	n/a		PRAC Recommendation - maintenance
II/0015	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	03/10/2024	n/a		
PSUSA/11010 /202402	Periodic Safety Update EU Single assessment - teclistamab	03/10/2024	n/a		PRAC Recommendation - maintenance

[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).

II/0009	Update of section 4.4 and 4.8 of the SmPC in order to update the warning on Progressive Multifocal Leukoencephalopathy (PML) based on a cumulative safety review and to include PML as new ADR with uncommon frequency. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/07/2024	11/08/2025	SmPC and PL	SmPC new text Progressive Multifocal Leukoencephalopathy (PML), which can be fatal, has also been reported in patients receiving TECVAYLI. Patients should be monitored for any new onset of or changes in pre-existing neurological signs or symptoms. If PML is suspected, treatment with TECVAYLI should be withheld and appropriate diagnostic testing initiated. If PML is confirmed, TECVAYLI must be discontinued. For more information, please refer to the Summary of Product Characteristics.
R/0010	Renewal of the marketing authorisation.	25/04/2024	13/06/2024		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 Tecvayli, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
II/0012	Update of sections 4.2, 4.8, 5.1 of the SmPC in order to amend the recommendations for dose delays, as well as, to update safety and efficacy information based on final results from study 64007957MMY1001 listed as a specific obligation in the Annex II (SOB/005); this is a phase 1/2, first in human, open	30/05/2024	11/08/2025	SmPC, Annex II and PL	Not applicable.

	label, dose escalation study of teclistamab in subjects with relapsed or refractory multiple myeloma. The Package Leaflet is updated accordingly. The RMP version 4.2 has also been submitted. In addition, the MAH took the opportunity to update Annex II and Annex IV of the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0013/G	This was an application for a group of variations. 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 B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	28/05/2024	11/08/2025	SmPC, Annex II and PL	
PSUSA/11010 /202308	Periodic Safety Update EU Single assessment - teclistamab	07/03/2024	n/a		PRAC Recommendation - maintenance
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	22/02/2024	n/a		
PSUSA/11010 /202302	Periodic Safety Update EU Single assessment - teclistamab	12/10/2023	07/12/2023	SmPC, Annex	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

				II and PL	PSUSA/11010/202302.
II/0006	Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update the posology recommendations to include the possibility of bi-weekly dosing, based on interim results from study 64007957MMY1001 (MajesTEC-1); this is a phase 1/2, single-arm, open-label, multicenter study of teclistamab administered as monotherapy to adult subjects with relapsed or refractory multiple myeloma. The Package Leaflet is updated accordingly. The RMP version 2.3 as also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and update the list of local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/07/2023	16/08/2023	SmPC, Annex II and PL	In patients who have a complete response or better for a minimum of 6 months with teclistamab 1.5 mg/kg SC once weekly, a reduced dosing frequency of 1.5 mg/kg SC every two weeks may be considered. For more information, please refer to the Summary of Product Characteristics.
R/0002	Renewal of the marketing authorisation.	25/05/2023	24/07/2023		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 Tecvayli, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	17/07/2023	n/a		

II/0003	Update of sections 4.2, 4.6 and 5.2 of the SmPC in order to revise the dosing schedule, amend recommendations on contraception and breast-feeding and to update pharmacokinetic information, based on the latest data available; the Package Leaflet is updated accordingly. 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.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/06/2023	16/08/2023	SmPC and PL	The dosing scheduling of teclistamab includes two step-up doses before the first full treatment or maintenance dose can be given. A gap between two and seven days is required between the different steps in this schedule and a minimum of five days between weekly maintenance doses must be maintained. Women of child-bearing potential should use effective contraception and are advised not to breats-feed during treatment and for five months after the final dose of teclistamab. For more information, please refer to the Summary of Product Characteristics.
IB/0004	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	19/05/2023	n/a		
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/01/2023	n/a		