Bavencio

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 /		10/04/2026		SmPC and PL	Immune mediated adverse reactions, which may be

[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/0000314741	Outcome: This was an application for a group of variations. 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 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 A grouped application comprised of 2 Type II Variations, as follows: C.I.4: Update of section 4.4 of the SmPC in order to update the warning on 'immune mediated adverse reactions', particularly regarding myositis, myocarditis, and myasthenia gravis (Triple-M syndrome), based on a safety review. The Package Leaflet is updated accordingly. C.I.4: Update of section 4.8 of the SmPC in order to update the frequency of 'sarcoidosis' in the list of adverse drug reactions (ADRs) for avelumab monotherapy from 'uncommon' to 'rare', and to add it to the list of ADRs for				severe or fatal, can occur in one or multiple organ systems or tissues simultaneously in patients treated with avelumab. Institute medical management promptly, including specialty consultation as appropriate, to address associated morbidity and risk of mortality. While immune mediated adverse reactions usually occur during treatment, symptoms can also manifest after discontinuation. Early identification and management of immune mediated adverse reactions are essential to ensure safe use of avelumab. Monitor patients for signs and symptoms of immune mediated adverse reactions. Cases of myocarditis myositis myasthenia gravis overlap syndrome (presenting as an overlap of either two or all three conditions), some with fatal outcome, have been reported with avelumab. Early recognition and aggressive management are essential to address associated morbidity and risk of mortality. For more information, please refer to the Summary of Product Characteristics.

	avelumab in combination with axitinib with frequency 'not known', based on a safety review. The Package Leaflet is updated accordingly. The RMP version 9.3 has been submitted. In addition, the MAH took the opportunity to introduce alignment changes to the PI.				
Variation type IB / EMA/VR/0000333535	Outcome: This was an application for a group of variations. Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.z Other variation - Accepted Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.z Other variation - Accepted	16/03/2026			

Variation type IB / EMA/VR/0000324359	Outcome: Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.d) Other change to an analytical procedure for a finished product (including replacement or addition) - Accepted	19/02/2026			
Variation type IA / EMA/VR/0000313566	Outcome: This was an application for a group of variations. 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 - To more accurately describe the appearance of active substance, starting material, intermediate or reagent - 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.d Deletion of a non-significant specification parameter	16/12/2025			

	(e.g. deletion of an obsolete parameter) - Accepted				
Variation type II / EMA/VR/0000279701	Outcome: 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 4.8 of the SmPC in order to add 'cytokine release syndrome' to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a safety assessment report. In addition, the MAH took the opportunity to introduce updates to the PI that include warning on polysorbate as well as statements on the use of the Patient Card in addition to administrative and editorial changes to the PI.	27/11/2025		SmPC and PL	
Variation type II / EMA/VR/0000261861	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	27/11/2025		SmPC and PL	

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4 and 4.8 of the SmPC in order to add "Gastritis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on postmarketing data and literature. The Package Leaflet is updated accordingly. The RMP version 9.1 has also been submitted.				
Variation type II / EMA/VR/0000289992	Outcome: This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.c The product is a biological/immunological medicinal product and the change requires an assessment of comparability - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.b Other changes to a test procedure (including replacement or addition) - Accepted B.II.e.4 Change in shape or dimensions of	23/10/2025			

	the container or closure (immediate packaging) - B.II.e.4.c Sterile medicinal products - Accepted B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.3 Sterile medicinal products and biological/ immunological medicinal products - Accepted 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.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted				
Variation type II / EMA/VR/0000244307	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study MS100070-0031 listed as a category 3 PASS in the RMP. This is a non-interventional	04/09/2025			

	cohort efficacy and safety study to assess the characteristics and management of patients with Merkel cell carcinoma (MCC) in Germany.				
Variation type IB / EMA/VR/0000285637	Outcome: This was an application for a group of variations. 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 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 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	25/07/2025			

Variation type IB / EMA/VR/0000272517	Outcome: 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.i Where there is no monograph in the European Pharmacopoeia or the national pharmacopoeia of a Member State for the active substance, a change in specification from in-house to a non-official Pharmacopoeia or a Pharmacopoeia of a third country - Accepted	28/05/2025			