Pluvicto

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
II/0022	Update of section 4.2, 4.4., 4.6 and 4.8 of the SmPC based on final results from study PSMA-617-01 (CAAA617A12301 – VISION) listed as a category 3 study in the RMP; this is an international, prospective, open-label, multicenter, randomized Phase 3 study of 177Lu-PSMA-617 in the treatment	08/05/2025		SmPC and PL	At the time of VISION final analysis, after a median follow-up duration of 14.2 months (range: 0.6 to 60.9 months), the overall safety profile remained consistent with that previously reported. For more information, please refer to the Summary of Product Characteristics.

[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).

	of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/11031 /202409	Periodic Safety Update EU Single assessment - lutetium (177LU) vipivotide tetraxetan	10/04/2025	n/a		PRAC Recommendation - maintenance
IB/0025	B.II.c.2.z - Change in test procedure for an excipient - Other variation	24/01/2025	n/a		
IB/0023/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.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	07/01/2025	n/a		
PSUSA/11031 /202403	Periodic Safety Update EU Single assessment - lutetium (177LU) vipivotide tetraxetan	31/10/2024	n/a		PRAC Recommendation - maintenance

N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/09/2024		PL	
IB/0020/G	This was an application for a group of variations. B.I.a.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size B.I.a.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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 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 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 B.I.a.2.a - Changes in the manufacturing process of	16/09/2024	n/a		

	the AS - Minor change in the manufacturing process of the AS 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				
IB/0018/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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	29/08/2024	n/a		
IB/0019	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	21/08/2024	n/a		

IA/0016/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/05/2024	n/a		

N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/04/2024		PL	
PSUSA/11031 /202309	Periodic Safety Update EU Single assessment - lutetium (177LU) vipivotide tetraxetan	11/04/2024	n/a		PRAC Recommendation - maintenance
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/03/2024		PL	
II/0010	B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier	07/12/2023	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2023	19/04/2024	PL	
IA/0011	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	20/11/2023	n/a		
PSUSA/11031 /202303	Periodic Safety Update EU Single assessment - lutetium (177LU) vipivotide tetraxetan	26/10/2023	n/a		PRAC Recommendation - maintenance
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/10/2023	19/04/2024	Labelling and PL	
IB/0008/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	20/09/2023	n/a		

	of the AS B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
II/0003	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	13/07/2023	n/a		
IB/0006/G	This was an application for a group of variations. 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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.1.a - Change in the manufacturer of AS or of a	06/07/2023	n/a		

	starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
IB/0002/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.c.3.z - Changes in the test procedure for the immediate packaging of AS - Other variation	11/05/2023	n/a		
IB/0004/G	This was an application for a group of variations. B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any	19/04/2023	19/04/2024	Annex II, Labelling and PL	

	manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site				
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/01/2023	19/04/2024	PL	