SCENESSE

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
S/0050	9th annual re-assessment	25/04/2024	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of SCENESSE should be maintained.

[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).

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II/0049	To remove study CUV-RCR-001 (Scenesse (Afamelanotide 16mg) Retrospective Chart Review) listed as an obligation in the Annex II of the Product Information. This is a retrospective study comparing long term safety data and outcome endpoints in patients receiving and not receiving Scenesse, or having discontinued Scenesse use. The Annex II and the RMP (version 9.11) are updated accordingly. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	11/04/2024		Annex II	In view of the infeasibility of the retrospective chart review (RCR) study due to the lack of patient recruitment and given that the vast majority of Erythropoietic Protoporphyria (EPP) patients is included in the registry study, listed as specific obligation for the marketing authorisation under exceptional circumstances of SCENESSE in the Annex II of the Product Information, which has the same objectives as the RCR and that these data are presented in annual reports to CHMP and PRAC, it is agreed that no significant additional knowledge gain is to be expected from the RCR. The EEDR runs with unlimited validity and data (including long-term safety data) have been collected for eight consecutive years now. Taking into consideration the above, it is considered that terminating the retrospective chart review study CUV-RCR-001 will not impact the benefit-risk of SCENESSE. Consequently, the obligation to conduct the retrospective chart review study is being removed from the Annex II of the Product Information.
IB/0051/G	This was an application for a group of variations. 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	19/03/2024	n/a		

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PSUSA/10314 /202306	Periodic Safety Update EU Single assessment - afamelanotide	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0048/G	This was an application for a group of variations. 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	21/11/2023	n/a		

	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				
IB/0046	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	29/08/2023	n/a		
S/0045	8th annual re-assessment	22/06/2023	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of SCENESSE should be maintained.
PSUSA/10314 /202206	Periodic Safety Update EU Single assessment - afamelanotide	12/01/2023	n/a		PRAC Recommendation - maintenance
II/0042	Submission of an updated RMP in order to update the allergy and hypersensitivity risk from potential to identified, following reported cases of positive allergy test results, confirming the causal association between the allergies to afamelanotide. Consequently, the RMP has been revised to reclassify the important potential risk Allergy and	27/10/2022	n/a		Not applicable

	hypersensitivity to important identified risk. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
S/0041	Annual re-assessment.	22/04/2022	n/a		
PSUSA/10314 /202106	Periodic Safety Update EU Single assessment - afamelanotide	13/01/2022	n/a		PRAC Recommendation - maintenance
IAIN/0040	A.1 - Administrative change - Change in the name and/or address of the MAH	04/01/2022	03/02/2023	PL	
IB/0038	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	02/09/2021	n/a		
II/0037	B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions	02/09/2021	n/a		
S/0035	6th annual re-assessment.	20/05/2021	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of SCENESSE should be maintained.

IA/0036	A.7 - Administrative change - Deletion of manufacturing sites	10/03/2021	n/a		
PSUSA/10314 /202006	Periodic Safety Update EU Single assessment - afamelanotide	14/01/2021	n/a		PRAC Recommendation - maintenance
II/0033	Update of section 4.8 of the SmPC to revise the frequencies of adverse drug reactions (ADRs) based on safety reports and to add new ADRS based on post-marketing spontaneous reports as requested during Scenesse Renewal procedure (EMEA/H/C/002548/R/0026); the Package Leaflet is updated accordingly. The revised RMP version 9.0 (in line with rev 2 of the template) is acceptable. In addition, the MAH took the opportunity to introduce minor editorial changes in section 2 of the SmPC and Annex IIIA. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/10/2020	09/12/2020	SmPC, Labelling and PL	As requested during Scenesse renewal procedure (EMEA/H/C/002548/R/0026) and based on post-marketing spontaneous reports, the MAH updated section 4.8 of the SmPC to add new ADRs, to revise frequency of known ADRs and to update some preferred terms in line with MedDRA. For further information, please refer to the SmPC. Additionally, 'administration site reactions' was removed from the list of safety concerns of the RMP.
S/0032	5th annual re-assessment	30/04/2020	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that the marketing authorisation under exceptional circumstances of Scenesse should be maintained.
PSUSA/10314 /201906	Periodic Safety Update EU Single assessment - afamelanotide	16/01/2020	n/a		PRAC Recommendation - maintenance

IB/0031/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.f.1.e - Stability of FP - Change to an approved stability protocol	16/12/2019	n/a		
IAIN/0030/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 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	12/12/2019	09/12/2020	Annex II and PL	

R/0026	Renewal of the marketing authorisation.	19/09/2019	19/11/2019	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of SCENESSE in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0028	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	19/07/2019	19/11/2019	SmPC, Annex II, Labelling and PL	
PSUSA/10314 /201812	Periodic Safety Update EU Single assessment - afamelanotide	11/07/2019	n/a		PRAC Recommendation - maintenance
S/0023	4th annual re-assessment	26/04/2019	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that the marketing authorisation under exceptional circumstances of Scenesse should be maintained.
IAIN/0027/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	12/04/2019	19/11/2019	SmPC, Annex II, Labelling and PL	

	A.7 - Administrative change - Deletion of manufacturing sites 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				
T/0024	Transfer of Marketing Authorisation	08/02/2019	20/03/2019	SmPC, Labelling and PL	
IB/0022	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 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	25/01/2019	n/a		
PSUSA/10314 /201806	Periodic Safety Update EU Single assessment - afamelanotide	17/01/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10314 /201712	Periodic Safety Update EU Single assessment - afamelanotide	12/07/2018	n/a		PRAC Recommendation - maintenance
S/0019	3rd annual re-assessment.	26/04/2018	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation

					of SCENESSE should be maintained.
II/0018	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	08/03/2018	n/a		
II/0017	B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	25/01/2018	n/a		
PSUSA/10314 /201706	Periodic Safety Update EU Single assessment - afamelanotide	11/01/2018	n/a		PRAC Recommendation - maintenance
IA/0015	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	10/08/2017	n/a		
PSUSA/10314 /201612	Periodic Safety Update EU Single assessment - afamelanotide	06/07/2017	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	10/05/2017	n/a		
S/0011	Annual re-assessment.	21/04/2017	n/a		
PSUSA/10314 /201606	Periodic Safety Update EU Single assessment - afamelanotide	12/01/2017	n/a		PRAC Recommendation - maintenance

PSUSA/10314 /201512	Periodic Safety Update EU Single assessment - afamelanotide	07/07/2016	n/a		PRAC Recommendation - maintenance
S/0007	1st Annual Re-assessment	26/05/2016	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that Marketing Authorisation of Scenesse should be maintained.
IA/0008	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	03/03/2016	n/a		
PSUSA/10314 /201506	Periodic Safety Update EU Single assessment - afamelanotide	14/01/2016	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	01/12/2015	12/08/2016	SmPC	
IA/0005	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	04/09/2015	n/a		
IAIN/0003/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	21/08/2015	n/a		

	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
IAIN/0002/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	27/07/2015	12/08/2016	SmPC, Annex II, Labelling and PL	
IB/0001	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	16/06/2015	n/a		