Skyclarys

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 / EMA/VR/0000357345	Outcome: C. Safety, efficacy, pharmacovigilance	03/09/2026		SmPC	As a result of this variation, sections 4.8 and 5.1 of the SmPC have been revised to update clinical

[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).

	changes - C.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 sections 4.8 and 5.1 of the SmPC in order to update clinical safety and efficacy information, based on final results from the open-label extension phase of the Phase 2 Study 408-C-1402; this is a Phase 2 study of the safety, efficacy, and pharmacodynamics of omaveloxolone in the treatment of Friedreich's ataxia				safety and efficacy information, based on the final results from the open-label extension of the Phase 2 Study 408-C-1402.
Variation type II / EMA/VR/0000357215	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.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 4.5 of the SmPC with CYP2C19-related Drug-Drug Interaction (DDI) information based on results from Study 296HV104; this is a Phase 1, Open-Label, Single-Sequence, 2-Period, DDI Study in Healthy Participants Evaluating the Effect of Omaveloxolone on the Pharmacokinetics of CYP2C19 Substrate, Omeprazole. The Package Leaflet is updated accordingly.	03/09/2026		SmPC and PL	Update of Annexes I and IIIB (section 4.5 of the SmPC and package leaflet)

Variation type II / EMA/VR/0000339477	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.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 sections 4.6 and 5.2 of the SmPC in order to update information on lactation, based on results from the phase 1 study 296HV101; this is an open-label, single dose study to assess the breast milk and plasma pharmacokinetics of omaveloxolone in healthy lactating women. The Package Leaflet is updated accordingly.	23/07/2026		SmPC and PL	Update of sections 4.6 and 5.2 of the SmPC in order to update information on lactation, based on results from the phase 1 study 296HV101; this is an open-label, single dose study to assess the breast milk and plasma pharmacokinetics of omaveloxolone in healthy lactating women. The Package Leaflet is updated accordingly.
Variation type IB / EMA/VR/0000350370	Outcome: Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.z Other variation - Accepted	26/06/2026			
Variation type II / EMA/VR/0000296476	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 5.3 of the SmPC in order	11/06/2026		SmPC	Update to Annex I preclinical information based on results from study RTA-P-21070 and to the RMP

	to update preclinical information based on results from study RTA-P-21070: this is a 104-week once daily oral gavage toxicity and toxicokinetic study with RTA 408 in rats. The RMP version 2.0 has also been submitted.				
Variation type IA / EMA/VR/0000339291	Outcome: Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.a) Minor change in the manufacturing process - Accepted	31/03/2026			
Variation type IB / EMA/VR/0000320215	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted	27/03/2026			
Variation type IB / EMA/VR/0000328186	Outcome: Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted	13/03/2026		SmPC	
Variation type IB / EMA/VR/0000326575	Outcome: Q.II.c.1 Change in the specification attribute and/or acceptance criteria of an excipient - Q.II.c.1.b) Addition of a new specification attribute to the specification with its corresponding analytical procedure - Accepted	06/03/2026			

Variation type IA / EMA/VR/0000323217	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	19/01/2026			
Variation type II / EMA/VR/0000263377	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.f Change outside the approved specifications limits range for the active substance - Accepted	04/12/2025			
Variation type IB / EMA/VR/0000292339	Outcome: This was an application for a group of variations. B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a	09/09/2025			

	Minor change in the manufacturing process of the active substance - Accepted				
Variation type IA_IN / EMA/VR/0000294883	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	03/09/2025		Annex II and PL	
Variation type IB / EMA/VR/0000276345	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted	24/07/2025			
Variation type IA_IN / EMA/VR/0000275830	Outcome: 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.a Secondary packaging site - Accepted	03/06/2025			
Variation type IA / EMA/VR/0000256186	Outcome: A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted	03/03/2025		SmPC	
PSUR / EMA/PSUR/0000274406	EURD: PSUSA/00000245/202502 Active substance: omaveloxolone Outcome: Maintenance	02/10/2025			Maintenance

PSUR / EMA/PSUR/0000311117	EURD: PSUSA/00000245/202508 Active substance: omaveloxolone Outcome: Maintenance	12/03/2026			maintenance
PSUR / EMA/PSUR/0000351082	EURD: PSUSA/00000245/202602 Active substance: omaveloxolone Outcome: Maintenance	01/10/2026			