Oxlumo

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/10884 /202211	Periodic Safety Update EU Single assessment - lumasiran	08/06/2023	n/a		PRAC Recommendation - maintenance
II/0014	Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study ALN-GO1; this is a 105-week s.c.	25/05/2023		SmPC and PL	SmPC new text Section 5.3 of the SmPC was amended to remove information on carcinogenicity studies.

[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).

	Carcinogenicity Study in Rats with Toxicokinetics. In addition, the MAH took the opportunity to implement editorial changes and to bring the PI in line with the latest QRD template version 10.3. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				For more information, please refer to the Summary of Product Characteristics.
IB/0015/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	04/04/2023	n/a		
IAIN/0012/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a	06/01/2023	n/a		

	manufacturing site for the FP - Secondary packaging site B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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 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) B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10884 /202205	Periodic Safety Update EU Single assessment - lumasiran	01/12/2022	n/a		PRAC Recommendation - maintenance
IA/0011	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/11/2022	n/a		
II/0008	Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to clarify administration instructions, include a caution warning for the treatment of severely renally impaired patients, update the description of adverse reactions injection site reactions, abdominal pain and immunogenicity, update efficacy, pharmacokinetic information based on interim results	15/09/2022		SmPC and PL	

	from a category 3 study in the RMP ILLUMINATE-C (ALN-GO1-005): A single arm study to evaluate efficacy, safety, pharmacokinetics, and pharmacodynamics of lumasiran in patients with advanced primary hyperoxaluria type 1 (PH1) and, in additon, based on available long-term efficacy and safety data from ongoing phase 3 studies ALN-GO1-003 in PH1 patients >6 years old and ALN-GO1-004 in PH1 patients <6 years old, and open-label extension study ALN-GO1-002. The Package Leaflet is updated accordingly. The RMP version 1.3 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10884 /202111	Periodic Safety Update EU Single assessment - lumasiran	10/06/2022	n/a		PRAC Recommendation - maintenance
II/0007	Update of section 5.3 of the SmPC in order to update the non-clinical information based on the final results from the 26-week GLP carcinogenicity study of lumasiran by s.c. injection in TgRasH2 mice, as agreed as part of protocol assistance (EMEA/H/SA/4014/2/2019/PA/PR/I). In addition, the MAH took the opportunity 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	09/12/2021	15/09/2022	SmPC and PL	There was no evidence of an increased incidence of neoplasia in the transgenic Tg-rasH2 mouse following repeated monthly administration of lumasiran for 26 weeks at doses of 150, 500 or 1500 mg/kg.

	data				
PSUSA/10884 /202105	Periodic Safety Update EU Single assessment - lumasiran	02/12/2021	n/a		PRAC Recommendation - maintenance
IA/0006	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/08/2021	15/09/2022	SmPC	
IA/0005	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)	20/08/2021	n/a		
IB/0003	B.II.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data	23/06/2021	n/a		
IB/0002	B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data	17/06/2021	n/a		
IB/0001/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	11/03/2021	n/a		