Qalsody

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 IB /	Outcome:	19/06/2026		SmPC	

[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/0000348686	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				
Variation type II / EMA/VR/0000296462	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 sections 4.8, 5.1, and 5.2 of the SmPC to numerically update the summary of safety profile and description of selected adverse reactions, as well as, to update clinical efficacy and pharmacokinetic information based on final integrated analysis from Study 233AS101 and Study 233AS102. Submission of the final results of Study 233AS102 is listed as a specific obligation in the Annex II and a category 2 study in the RMP. Study 233AAS102 was an open label extension study to assess the long-term safety, tolerability, pharmacokinetics, and effect on disease progression of tofersen administered to previously treated adults with amyotrophic lateral sclerosis caused by superoxide dismutase 1 mutation. The RMP has been	12/03/2026		SmPC and Annex II	Section 4.8 is updated to include safety results from the based on final integrated analysis from Study 233AS101 and Study 233AS102. In particular the summary of safety profile is updated as follows: the serious adverse reactions in tofersen-treated participants were myelitis (4.1%), increase intracranial pressure and/or papilloedema (2.7%), radiculitis (1.4%) and aseptic meningitis (1.4%). The most common adverse reactions reported in tofersen-treated participants who received 100 mg (n=147) were pain (68.7%), arthralgia (36.7%), fatigue (30.6%), CSF white blood cell increased (27.9%), CSF protein increased (26.5%), myalgia (22.4%) and pyrexia (20.4%). The description of selected adverse reaction myelitis and/or radiculitis is also updated. Section 5.1 is updated to include efficacy results from the based on final integrated analysis from Study 233AS101 and Study 233AS102. At the time of the final integrated analysis 33.3% of participants in the placebo/delayed-start group and 47.2% of participants in the early-start group completed Study 102, with a median opportunity for follow-up across the two studies of 4.9 years (range: 3.6 to 5.4 years). Earlier initiation of tofersen (ES group) was associated with trends for reduction in decline

	updated to version 1.2.				on ALSFRS R, SVC percent predicted, and HHD megascore as compared to placebo/delayed initiation of tofersen (DS group), although the differences were not statistically significant. Earlier initiation of tofersen (ES group) was associated with an apparent reduction in the risk of death or permanent ventilation. Section 5.2 is updated to include pharmacokinetic information from the based on final integrated analysis from Study 233AS101 and Study 233AS102. The following subsections were updated: distribution, elimination, and immunogenicity. For more information, please refer to the Summary of Product Characteristics.
Annual reassessment - H / EMA/S/0000275049	Outcome: Based on the efficacy and safety data collected as part of the specific obligation(s) during the period covered by this annual re-assessment, the benefit-risk balance of Qalsody in its approved indication(s) (please refer to the Summary of Product Characteristics) remains favourable.	13/11/2025			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 Qalsody should be maintained.
Variation type IA / EMA/VR/0000307320	Outcome: This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities	21/10/2025			

	for which the manufacturer/importer is responsible do not include batch release - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IA / EMA/VR/0000304401	Outcome: This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance,	15/10/2025			

	starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000296858	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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	22/09/2025			
PASS / EMA/PASS/0000264233	Outcome: Based on the PRAC review of the PASS protocol version 3.0 and in accordance with Article 107n(2)(b)(ii) of Directive 2001/83/EC, the PRAC considers that the study is non-interventional and that the protocol for the PASS entitled an observational registry-based study utilising data from two disease registry networks PRECISION ALS and ALS/MND NHC to evaluate the long-term safety of tofersen in people with SOD1-ALS can be endorsed.	04/09/2025			

Variation type IB / EMA/VR/0000279682	Outcome: B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.c Liquid active substances (non sterile) - Accepted	14/07/2025			
Variation type IA_IN / EMA/VR/0000262547	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	27/03/2025			
PSUR / EMA/PSUR/0000327929	EURD: PSUSA/00011064/202510 Active substance: tofersen Outcome: Maintenance	11/06/2026			
PSUR / EMA/PSUR/0000288271	EURD: PSUSA/00011064/202504 Active substance: tofersen Outcome: Maintenance	27/11/2025			Maintenance