LYFNUA

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/0003/G	This was an application for a group of variations. Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information from the multicentre randomised study MK-7264-043 in patients with refractory or unexplained chronic cough and add 'headache' to the list of adverse drug reactions (ADRs) with frequency common. In	03/04/2025		SmPC and PL	Refractory or unexplained chronic cough of recent onset The efficacy of Lyfnua in adults with RCC or UCC of recent onset was assessed in a multicentre, randomised, double-blind, placebo-controlled study (NCT04193202). Recent onset is defined as having RCC or UCC for > 8 weeks but < 12 months. The primary objective of the study was to demonstrate that

[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).

	addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor 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 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Lyfnua was effective in improving cough-specific health-related quality of life, measured as change from baseline in LCQ total score at 12 weeks. Patients were randomised to twice daily doses of Lyfnua 45 mg or placebo. Patients enrolled in the study were current non-smokers, not on ACE-inhibitors, diagnosed with RCC or UCC, had a score of ≥ 40 mm on the cough severity VAS, and had a chronic cough for < 12 months. Most patients were female (65%), white (72%), and from Europe (59%) with a mean age of 53 years (range 18 to 83 years). A total of 70.8% of patients were diagnosed with RCC, 29.2% with UCC, and the mean duration of chronic cough was 7.2 months. For more information, please refer to the Summary of Product Characteristics.
PSUSA/132/202407	Periodic Safety Update EU Single assessment - gefapixant	13/02/2025	n/a		PRAC Recommendation - maintenance
PSUSA/132/202401	Periodic Safety Update EU Single assessment - gefapixant	05/09/2024	n/a		PRAC Recommendation - maintenance
IB/0001/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary	26/04/2024	n/a		

	packaging, for non-sterile medicinal products				