Zokinvy

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
Annual reassessment - H /		29/01/2026			

[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/S/0000306613					
Variation type II / EMA/VR/0000269652	This was an application for a group of variations. 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 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 A grouped application consisting of: C.I.4: Update of sections 4.4 and 4.5 in order to add two new warnings regarding QTc Interval Prolongation and OCT1 substrates as anti-arrhythmic medicinal products and other substances that may prolong the QT interval, based on results from study EIG-LNF-022. This is a Phase 1, double-blind, randomized, placebo- and active-control, parallel-group, high-precision QTc study evaluating the effects of multiple-dose lonafarnib on cardiac repolarization in healthy male and female volunteers. The Package Leaflet is updated accordingly. C.I.4: Update of sections 5.2 and 6.6 in	20/11/2025		SmPC and PL	Significant QTc prolongation has been observed in healthy volunteers after multiple supratherapeutic lonafarnib dose administrations. Because of this and because QTc interval prolongation is known to be associated with Hutchinson-Gilford progeria syndrome itself, warnings and dosing guidance on potential QTc interval prolongation, and avoidance of co-administration of lonafarnib with other QT-prolonging agents, have been included in the SmPC. Based on the additional new data, lonafarnib may be administered with mashed banana, yogurt, or semolina porridge, as well as orange juice. For more information, please refer to the Summary of Product Characteristics.

	order to add information regarding soft food options based on results from studies EIG-LNF-019 and EIG-LNF-020. EIG-LNF-019 is a Phase 1, Single-Center, Single-Sequence, 3-Period Crossover, Relative Bioavailability Study with Single-Dose Lonafarnib Suspension Formulation, Single-Dose Lonafarnib Mixed with Applesauce, and Single-Dose Lonafarnib Intact Capsule Formulation in Healthy Subjects; and EIG-LNF-020 is a Phase 1, Single-Center, Single-Sequence, 6-Period Crossover, Relative Bioavailability Study with Single-Dose Lonafarnib Mixed with 5 Different Soft Foods and Single-Dose Lonafarnib Intact Capsule Formulation in Healthy Subjects. The Package Leaflet is updated accordingly.				
Variation type IA_IN / EMA/VR/0000248228	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	11/02/2025			
PSUR / EMA/PSUR/0000296604					Maintenance
PSUR / EMA/PSUR/0000248976					Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing lonafarnib remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).