23 July 2026
EMADOC-1829012207-57973
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Lyrokaul

## Lerodalcibep

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lyrokaul, intended for the treatment of adult patients with hypercholesterolaemia and mixed dyslipidaemia.

The applicant for this medicinal product is LIB Therapeutics B.V.

Lyrokaul will be available as 300 mg solution for injection pre-filled syringes. The active substance of Lyrokaul is lerodalcibep, a lipid modifying agent (ATC code: C10AX19). Lerodalcibep is a fusion protein that binds proprotein convertase subtilisin/kexin type 9 (PCSK9). PCSK9 binds to LDLR on the surface of hepatocytes to promote LDLR degradation within the liver. By inhibiting the binding of PCSK9 to LDLR, lerodalcibep prevents the degradation of the LDLR and increases its recycling and the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.

The benefits of Lyrokaul are its ability to reduce the levels of serum LDL-cholesterol in patients whose cholesterol is not under control despite a maximum tolerated dose of statins, or who cannot take statins. The most common side effects are injection site reactions.

The full indication is:

LYROKAUL is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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languages after the marketing authorisation has been granted by the European Commission.