

MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-102590-PIP01-26-M01

Scope of the Application

Active Substance(s)

Lerodalcibep

Condition(s)

Treatment of hypercholesterolaemia, Treatment of mixed dyslipidaemia

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

LIB Therapeutics B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, LIB Therapeutics B.V. submitted to the licensing authority on 23/07/2026 15:05 BST an application for a Modification

The procedure started on 28/07/2026 14:45 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-102590-PIP01-26-M01

Of 29/07/2026 09:27 BST

On the adopted decision for Lerodalcibep (MHRA-102590-PIP01-26-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Lerodalcibep, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to LIB Therapeutics B.V., Eurogate III, Watermanweg 20-36, Rotterdam, NETHERLANDS, 3067 GG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hypercholesterolaemia. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. 1.2 Condition: Treatment of mixed dyslipidaemia. The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hypercholesterolaemia.

2.2 Indication(s) targeted by the PIP:

Treatment of elevated low-density lipoprotein-cholesterol (LDL-C) in children from 6 to less than 18 years of age with heterozygous familial hypercholesterolaemia or with homozygous familial hypercholesterolaemia.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development in accordance with the EU Medical Device Regulation (MDR) of a 300mg strength in pre-filled syringe to be delivered via an auto-injector.
Non-Clinical Studies	1	Study 2 (LIB003.TX.009) Study to assess the potential maternal and developmental effects of lerodalcibep in pregnant cynomolgus monkeys and their offspring
Clinical Studies	3	Study 3 (LIB003-008) Double-blind, randomised, placebo-controlled study to assess the efficacy, safety and pharmacokinetics (PK) of lerodalcibep in patients from 6 to less than 18 years of age with heterozygous familial hypercholesterolemia (HeFH). Study 4 (LIB003-003) Open-label, randomised, cross-over study to compare efficacy of lerodalcibep with evolocumab in patients from 10 to less than 18 years of age with homozygous familial hypercholesterolemia (HoFH) on stable diet and oral LDL-C-lowering drug therapy. Study 5 (LIB003-007)

		Open-label extension study to assess the long-term safety, tolerability and efficacy in patients HoFH, HeFH, cardiovascular disease (CVD) or at high risk of CVD on stable diet and oral LDL-C-lowering drug therapy.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/09/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes