EMADOC-1700519818-1766926

European Medicines Agency decision

EMA/PE/0000181518

of 6 December 2024

on the acceptance of a modification of an agreed paediatric investigation plan for lerodalcibep in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for lerodalcibep in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0370/2020 issued on 9 September 2020,

Having regard to the application submitted by LIB Therapeutics Inc. on 19 June 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lerodalcibep, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to LIB Therapeutics Inc., 5375 Medpace Way, Cincinnati, OH - 45227-1543, USA.

EMADOC-1700519818-1616977
Amsterdam, 18 October 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000181518

Scope of the application

Active substance(s):

Lerodalcibep

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypercholesterolaemia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

LIB Therapeutics Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LIB Therapeutics Inc. submitted to the European Medicines Agency on 19 June 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0370/2020 issued on 9 September 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 19 August 2024.

Scope of the modification

The timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, by consensus:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

Case number: **EMA/PE/0000181518**

Lerodalcibep for **Treatment of hypercholesterolaemia**

1. Waivers by subset

From (age or stage)	To (age or stage)	Legal ground(s) for waiver
Birth	Less than 6 years	For solution for injection, subcutaneous use: the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan - studies summary

Study	Study type	Study name/description
Study 1	Quality measure	Development in accordance with the EU Medical Device Regulation (MDR) of a 300 mg dose in pre-filled syringe to be delivered via an auto-injector (AI)
Study 2: LIB003.TX.009	Non-clinical study	Study to assess the potential maternal and developmental effects of lerodalcibep in pregnant cynomolgus monkeys and their offspring.
Study 3: LIB003-008	Clinical study	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	Clinical study	Open-label, randomized, 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	Clinical study	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.

3. Paediatric Investigation Plan - deferrals and follow-up

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.