EMA/598851/2020

European Medicines Agency decision

P/0440/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for tralokinumab (EMEA-001900-PIP02-17-M04) 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 tralokinumab (EMEA-001900-PIP02-17-M04) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0083/2018 issued on 16 March 2018, the decision P/0250/2018 issued on 15 August 2018, the decision P/0104/2019 issued on 25 March 2019, and the decision P/0145/2020 issued on 15 April 2020,

Having regard to the application submitted by LEO Pharma A/S on 9 July 2020 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 16 October 2020, 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.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for tralokinumab, solution for injection, subcutaneous use, 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 LEO Pharma A/S, Industriparken 55, 2750 – Ballerup, Denmark.

EMA/PDCO/410150/2020
Amsterdam, 16 October 2020

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

EMEA-001900-PIP02-17-M04

Scope of the application

Active substance(s):

Tralokinumab

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

LEO Pharma A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LEO Pharma A/S submitted to the European Medicines Agency on 9 July 2020 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/0083/2018 issued on 16 March 2018, the decision P/0250/2018 issued on 15 August 2018, the decision P/0104/2019 issued on 25 March 2019, and the decision P/0145/2020 issued on 15 April 2020.

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

The procedure started on 18 August 2020.

Scope of the modification

Some measures 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:

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

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

2. The measures and timelines of the 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 annex 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)

1. Waiver

1.1. Condition

Treatment of atopic dermatitis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 2 years of age;
- solution for injection, subcutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate-to-severe atopic dermatitis in adolescents (12–17 years) who are candidates for systemic treatment

Treatment of severe atopic dermatitis in children (2–11 years) who are candidates for systemic treatment

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 1** Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of tralokinumab compared to placebo in adolescents with moderate-to-severe atopic dermatitis

		Study 2 Assessor-blind, randomised trial to evaluate PK and safety of tralokinumab in children from 2 to less than 12 years of age with severe atopic dermatitis **Study 3** Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of tralokinumab as add-on to standard of care compared to placebo in children from 2 to 12 years of age with severe atopic dermatitis
Extrapolation, modelling and simulation studies	2	**Study 4** Modelling and simulation study to support the dose selection for PK & safety trial in children (Study 2) **Study 5** Modelling and simulation study to support the dose selection for efficacy & safety trial in children (Study 3)
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes