EMA/386576/2021

European Medicines Agency decision

P/0286/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for lebrikizumab (EMEA-002536-PIP01-18-M01) 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 lebrikizumab (EMEA-002536-PIP01-18-M01) 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/0151/2020 issued on 17 April 2020,

Having regard to the application submitted by Eli Lilly and Company Limited on 22 March 2021 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 25 June 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lebrikizumab, solution for injection, subcutaneous use, 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 Eli Lilly and Company Limited, 8 Arlington Square West, Downshire Way, RG12 1PU – Bracknell, United Kingdom.

EMA/PDCO/183713/2021
Amsterdam, 25 June 2021

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

EMEA-002536-PIP01-18-M01

Scope of the application

Active substance(s):

Lebrikizumab

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:

Eli Lilly and Company Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted to the European Medicines Agency on 22 March 2021 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/0151/2020 issued on 17 April 2020.

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

The procedure started on 27 April 2021.

Scope of the modification

Some measures and 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:

   - 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 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:

- the paediatric population from birth to less than 6 months of age;
- solution for injection, subcutaneous use;
- 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:

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severe atopic dermatitis (AD) inadequately controlled by prescription topical medications

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

From 6 months 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	6	**Study 1** Randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe atopic dermatitis (AD). (DRM06-AD04)

		Study 2 Randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe AD. (DRM06-AD05) **Study 3** Randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab when used in combination with topical corticosteroid treatment in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe atopic dermatitis (AD). (DRM06-AD06) **Study 4** Randomized, double-blind, placebo controlled study to evaluate PK, efficacy and safety of lebrikizumab in patients from 6 months to less than 12 years of age and patients from 12 years to less than 18 years of age who weigh less than 40 kg with moderate to severe atopic dermatitis. (DRM06-AD13) **Study 5** Study deleted as part of procedure EMEA-002536-PIP01-18-M01 **Study 6** Open-label, single-arm study to assess the safety and efficacy of lebrikizumab in adolescent patients from 12 years to less than 18 years with moderate-to-severe atopic dermatitis. (DRM06-AD17)
Extrapolation, modelling and simulation studies	2	**Study 7** Dose finding population PK model to estimate doses in patients from 6 years to less than 18 years of age (DRM06-Model study 1) **Study 8** Dose finding population PK model to estimate doses in patients from 6 months to less than 6 years of age (DRM06-Model study 2)
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:	No
Date of completion of the paediatric investigation plan:	By April 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes