

EMA/173225/2020

European Medicines Agency decision

P/0151/20

of 17 April 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for lebrikizumab (EMA-002536-PIP01-18) 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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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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Dermira Inc. on 23 April 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for lebrikizumab, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for lebrikizumab, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for lebrikizumab, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Dermira Inc., 275 Middlefield Road, Suite 150, 94025 - Menlo Park, California, United States.

EMA/PDCO/684653/2019
Amsterdam, 28 February 2020

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-002536-PIP01-18

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:

Dermira Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Dermira Inc. submitted for agreement to the European Medicines Agency on 23 April 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 28 May 2019.

Supplementary information was provided by the applicant on 29 November 2019. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member 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 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;
- 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.

Area	Number of measures	Description
Clinical studies	6	<p>Study 1</p> <p>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)</p> <p>Study 2</p> <p>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)</p> <p>Study 3</p> <p>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)</p> <p>Study 4</p> <p>Randomized, double-blind, placebo controlled study to evaluate PK, efficacy and safety of lebrikizumab in patients from 6 years 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)</p> <p>Study 5</p> <p>Randomized, double-blind, placebo controlled study to evaluate PK, efficacy and safety of lebrikizumab in patients from 6 months to less than 6 years of age with moderate to severe atopic dermatitis. (DRM06-AD14)</p> <p>Study 6</p> <p>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)</p>
Extrapolation, modelling and simulation studies	2	<p>Study 7</p> <p>Dose finding population PK model to estimate doses in patients from 6 years to less than 18 years of age (DRM06-Model study 1)</p> <p>Study 8</p> <p>Dose finding population PK model to estimate doses in patients from 6 months to less than 6 years of age (DRM06-Model study 2)</p>

Area	Number of measures	Description
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 September 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes