EMA/94228/2021

European Medicines Agency decision

P/0108/2021

of 17 March 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for delgocitinib (EMEA-002329-PIP02-20) 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 726/2004[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 application submitted by LEO Pharma A/S on 21 February 2020 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 29 January 2021, 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 delgocitinib, cream, cutaneous 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 delgocitinib, cream, cutaneous 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 delgocitinib, cream, cutaneous 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 LEO Pharma A/S, Industriparken 55, 2750 – Ballerup, Denmark.

EMA/PDCO/602541/2020
Amsterdam, 29 January 2021

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

EMEA-002329-PIP02-20

Scope of the application

Active substance(s):

Delgocitinib

Condition(s):

Treatment of dermatitis and eczema

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

LEO Pharma A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, LEO Pharma A/S submitted for agreement to the European Medicines Agency on 21 February 2020 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 31 March 2020.

Supplementary information was provided by the applicant on 23 October 2020. 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 dermatitis and eczema

The waiver applies to:

- the paediatric population from birth to less than 3 months of age;
- cream, cutaneous 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 dermatitis and eczema

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic hand eczema

Treatment of atopic dermatitis

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

From 3 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cream.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of lower strength appropriate for children from 3 months of age
Non-clinical studies	3	**Study 2** Dose range-finding juvenile toxicity study in minipigs to evaluate pharmacokinetic profile of delgocitinib (77052) **Study 3** Definitive juvenile toxicity study in rats to evaluate toxicity of delgocitinib (SB95TY)

Area	Number of measures	Description
		Study 4 Reprotox: (enhanced) pre- and postnatal development in rats to evaluate adverse effects on the pregnant/lactating females and on development of the conceptus and the offspring (R-1208)
Clinical studies	7	**Study 5** Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate safety and efficacy of delgocitinib cream in adolescents from 12 to less than 18 years of age with moderate to severe chronic hand eczema (LP0133-1426) **Study 6** Open-label, uncontrolled trial to evaluate PK and safety of delgocitinib cream in children from 2 to less than 18 years of age (and adults) with moderate to severe atopic dermatitis (LP0133-1181) **Study 7** Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate efficacy and safety of delgocitinib cream in children from 2 to less than 18 years of age (and adults) with mild to severe atopic dermatitis (LP0133-1404) **Study 8** Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate efficacy and safety of delgocitinib cream in children from 2 to less than 18 years of age (and adults) with mild to severe atopic dermatitis (LP0133-1405) **Study 9** Open-label, single-arm long-term extension trial to evaluate the long-term safety of delgocitinib cream in children from 2 to less than 18 years of age (and adults) with AD completing the LP0133-1404 and LP0133-1405 trials (LP0133-1406) **Study 10** Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate efficacy and safety of delgocitinib cream in children from 3 months to less than 2 years of age with mild to severe atopic dermatitis (LP0133-1423), including a separate open-label cohort for PK assessment **Study 11** Double-blind, double-dummy, randomised, 2-arm, active-controlled, parallel-group trial to evaluate efficacy and safety of delgocitinib cream in children from 12 to less than 18 years of age (and adults) with mild to severe atopic dermatitis (LP0133-2176)

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	0	Not applicable.
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 December 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes