EMA/562870/2023

European Medicines Agency decision

P/0533/2023

of 29 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for delgocitinib (EMEA-002329-PIP02-20-M03) 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 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/0108/2021 issued on 17 March 2021, the decision P/0098/2022 issued on 11 March 2022 and the decision P/0136/2023 issued on 14 April 2023.

Having regard to the application submitted by LEO Pharma A/S on 4 August 2023 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 10 November 2023, 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 delgocitinib, cream, cutaneous 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 LEO Pharma A/S, Industriparken 55, 2750 - Ballerup, Denmark.

EMA/PDCO/375248/2023
Amsterdam, 10 November 2023

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

EMEA-002329-PIP02-20-M03

Scope of the application

Active substance(s):

Delgocitinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic hand 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 22 of Regulation (EC) No 1901/2006 as amended, LEO Pharma A/S submitted to the European Medicines Agency on 4 August 2023 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/0108/2021 issued on 17 March 2021, the decision P/0098/2022 issued on 11 March 2022 and the decision P/0136/2023 issued on 14 April 2023.

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

The procedure started on 11 September 2023.

Scope of the modification

Some 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 Paediatric Committee member of Norway 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 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)

1. Waiver

1.1. Condition:

Treatment of chronic hand eczema

The waiver applies to:

- the paediatric population from birth to less than 12 years 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 chronic hand eczema

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic hand eczema

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Deleted during procedure EMEA-002329-PIP02-20-M01
Non-clinical studies	**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)

	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	**Study 5** Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate safety and efficacy of delgocitinib cream in adolescents from 12 years to less than 18 years of age with moderate to severe chronic hand eczema (LP0133-1426) **Study 6** Deleted during procedure EMEA-002329-PIP02-20-M01 **Study 7** Deleted during procedure EMEA-002329-PIP02-20-M01 **Study 8** Deleted during procedure EMEA-002329-PIP02-20-M01 **Study 9** Deleted during procedure EMEA-002329-PIP02-20-M01 **Study 10** Deleted during procedure EMEA-002329-PIP02-20-M01 **Study 11** Deleted during procedure EMEA-002329-PIP02-20-M01
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 2024
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.