EMA/282809/2023

European Medicines Agency decision

P/0277/2023

of 14 July 2023

on the acceptance of a modification of an agreed paediatric investigation plan for nemolizumab (EMEA-001624-PIP01-14-M06) 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/0106/2015 issued on 13 May 2015, the decision P/0253/2021 issued on 9 July 2021, the decision P/0545/2021 issued on 4 January 2022 and the decision P/0201/2022 issued on 21 June 2022,

Having regard to the application submitted by Galderma International S.A.S on 17 February 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 26 May 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 nemolizumab, powder for 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 Galderma International S.A.S, La Défense 4, Tour Europlaza, 20 avenue André Prothin, 92927 - Paris La Défense cedex, France.

EMA/PDCO/96247/2023
Amsterdam, 26 May 2023

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

EMEA-001624-PIP01-14-M06

Scope of the application

Active substance(s):

Nemolizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Galderma International S.A.S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Galderma International S.A.S submitted to the European Medicines Agency on 17 February 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/0106/2015 issued on 13 May 2015, the decision P/0253/2021 issued on 9 July 2021, the decision P/0545/2021 issued on 4 January 2022 and the decision P/0201/2022 issued on 21 June 2022.

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

The procedure started on 27 March 2023.

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 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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- powder for 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 not adequately controlled with topical treatments

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of age-appropriate pharmaceutical form
Non-clinical studies	**Study 2** Study to evaluate the effects on pre- and postnatal development in cynomolgus monkeys and to assess the systemic exposure in dams and offspring along with milk concentrations (SBL036-185, TOX14.0140)
Clinical studies	**Study 3** Placebo-controlled, randomized, multicentre, study to evaluate efficacy and safety of nemolizumab (SPR.118161)

	Study 4 Placebo-controlled, randomized, multicentre, study to evaluate efficacy and safety of nemolizumab (SPR.118169) **Study 5** Single arm, open label, long-term study to evaluate efficacy and safety of nemolizumab (SPR.118163) **Study 6** *Deleted during procedure EMEA-001624-PIP01-14-M04* **Study 7** *Deleted during procedure EMEA-001624-PIP01-14-M05* **Study 8** *Deleted during procedure EMEA-001624-PIP01-14-M05* **Study 9** Deleted during procedure EMEA-001624-PIP01-14-M05 **Study 11** *Added during procedure EMEA-001624-PIP01-14-M03* Single-arm, open-label study to evaluate PK, safety and activity of nemolizumab in adolescents with moderate to severe atopic dermatitis (SPR.116912) **Study 12** *Added during procedure EMEA-001624-PIP01-14-M05* Single-arm, open-label trial to evaluate pharmacokinetics (PK), safety and activity of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis (SPR.118126) **Study 13** *Added during procedure EMEA-001624-PIP01-14-M05* Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis (SPR.204784) **Study 14** *Added during procedure EMEA-001624-PIP01-14-M05* Open-label, long-term, extension trial to evaluate safety and activity of nemolizumab in children from 2 years to less than 12 years with moderate to severe atopic dermatitis (SPR.205513)
Extrapolation, modelling and simulation studies	**Study 10** 1-compartment model with 1st order absorption (PK)
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 April 2029
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.