EMA/709753/2021

European Medicines Agency decision

P/0545/2021

of 4 January 2022

on the acceptance of a modification of an agreed paediatric investigation plan for nemolizumab (EMEA-001624-PIP01-14-M04) 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 nemolizumab (EMEA-001624-PIP01-14-M04) 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/0106/2015 issued on 13 May 2015 and the decision P/0253/2021 issued on 9 July 2021,

Having regard to the application submitted by Galderma International S.A.S. on 6 August 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 12 November 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 nemolizumab, powder for 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 Galderma International S.A.S, Tour Europlaza, 20 avenue André Prothin, La Défense 4, 92927 - Paris La Défense cedex, France.

EMA/PDCO/468246/2021
Amsterdam, 12 November 2021

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

EMEA-001624-PIP01-14-M04

Scope of the application

Active substance(s):

Nemolizumab

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 6 August 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/0106/2015 issued on 13 May 2015 and the decision P/0253/2021 issued on 9 July 2021.

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

The procedure started on 14 September 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 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 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age-appropriate pharmaceutical form.
Non-clinical studies	1	**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.

Clinical studies	7	**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** Randomised, double-blind, placebo-controlled, multicentre, single dose study to evaluate systemic exposure and tolerability profile of nemolizumab. **Study 8** Single arm, open label, repeat dose extension study. **Study 9** Single arm, open label, long-term study. **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)
Extrapolation, modelling and simulation studies	1	**Study 10** 1-compartment model with 1st order absorption (PK).
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 March 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes