EMA/300768/2015

European Medicines Agency decision

P/0122/2015

of 5 June 2015

on the acceptance of a modification of an agreed paediatric investigation plan for dupilumab (EMEA-001501-PIP01-13-M01) 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 dupilumab (EMEA-001501-PIP01-13-M01) 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/0169/2014 issued on 7 July 2014,

Having regard to the application submitted by Regeneron Pharmaceuticals, Inc on 21 January 2015 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 17 April 2015, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 dupilumab, 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 Regeneron Pharmaceuticals, Inc, 777 Old Saw Mill River RD, 10591 - Tarrytown, United States of America.

Done at London, 5 June 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/72176/2015
London, 17 April 2015

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

EMEA-001501-PIP01-13-M01

Scope of the application

Active substance(s):

Dupilumab

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:

Regeneron Pharmaceuticals, Inc

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Regeneron Pharmaceuticals, Inc submitted to the European Medicines Agency on 21 January 2015 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/0169/2014 issued on 7 July 2014.

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

The procedure started on 17 February 2015.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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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 in the scope set out in the Annex I of this opinion.

   The Icelandic and the Norwegian Paediatric Committee members agree 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 6 months;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of atopic dermatitis

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 studies	Description
Quality-related studies	1	**Study 1** Development of an age appropriate strength/presentation for smaller children below 3 years of age.
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 2** Open-Label study to characterize the safety and PK of a single administration of dupilumab in paediatric patients from 6 to less than 18 years of age. **Study 3** Randomized, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in pediatric patients with moderate to severe (from 12 to less than 18 years of age) or severe (from 6 to less than 12 years of age) atopic dermatitis.

		Study 4 Open-Label study to characterize the safety and PK of a single administration of dupilumab in paediatric patients from 6 to less than 18 years of age. **Study 5** Randomized, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in pediatric patients (from 6 months to less than 6 years of age) atopic dermatitis whose disease cannot be adequately controlled with topical medications.
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 July 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes