EMA/120432/2017

European Medicines Agency decision

P/0069/2017

of 3 April 2017

on the acceptance of a modification of an agreed paediatric investigation plan for dupilumab (EMEA-001501-PIP01-13-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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on the acceptance of a modification of an agreed paediatric investigation plan for dupilumab (EMEA-001501-PIP01-13-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/0169/2014 issued on 7 July 2014, the decision P/0122/2015 issued on 5 June 2015, the decision P/0072/2016 issued on 18 March 2016 and the decision P/0219/2016 issued on 12 August 2016.

Having regard to the application submitted by Regeneron Pharmaceuticals, Inc on 4 November 2016 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 24 March 2017, 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 following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006 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 dupilumab, 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 Regeneron Pharmaceuticals, Inc, 777 Old Saw Mill River Road, 10595 - Tarrytown, USA.

EMA/PDCO/155091/2017
London, 24 March 2017

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

EMEA-001501-PIP01-13-M04

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 on4 November 2016 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 decision P/0122/2015 issued on 5 June 2015, the decision P/0072/2016 issued on 18 March 2016 and the decision P/0219/2016 issued on 12 August 2016.

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

An Opinion was adopted by the Paediatric Committee on 27 January 2017. Regeneron Pharmaceuticals, Inc received the Paediatric Committee Opinion on 6 February 2017.

On 1 March 2017 Regeneron Pharmaceuticals, Inc submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 2 March 2017.

A meeting with the Paediatric Committee took place on 22 March 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures and the timelines of the paediatric investigation plan and the timelines of the deferral in the scope set out in the Annex I of this opinion;

1.2. following re-examination, to amend the scope of the modifications of the paediatric investigation plan.

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 subsets of the paediatric population and condition 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	5	**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 paediatric patients from 12 to less than 18 years of age with moderate to severe atopic dermatitis **Study 4** Study to evaluate the safety, pharmacokinetics (PK) and efficacy of dupilumab in patients from 6 months to less than 6 years of age with severe atopic dermatitis (AD) **Study 5** Randomized, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in paediatric patients (from 6 years to less than 12 years of age) with severe atopic dermatitis **Study 6** Randomized, double-blind, placebo controlled study to assess the efficacy of dupilumab in paediatric patients (from 6 months to less than 6 years of age) with severe atopic dermatitis
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 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes