EMA/38339/2017

European Medicines Agency decision

P/0021/2017

of 3 February 2017

on the acceptance of a modification of an agreed paediatric investigation plan for dupilumab (EMEA-001501-PIP02-13-M02) 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-PIP02-13-M02) 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/0192/2014 issued on 6 August 2014, and the decision P/0160/2015 issued on 13 July 2015,

Having regard to the application submitted by Sanofi-Aventis Recherche & Développement on 23 September 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 16 December 2016, 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 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 Sanofi-Aventis Recherche & Développement, 1, avenue Pierre Brossolette, 91385 - Chilly-Mazarin, France.

EMA/PDCO/653999/2016
London, 16 December 2016

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

EMEA-001501-PIP02-13-M02

Scope of the application

Active substance(s):

Dupilumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi-Aventis Recherche & Développement

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-Aventis Recherche & Développement submitted to the European Medicines Agency on 23 September 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/0192/2014 issued on 6 August 2014, and the decision P/0160/2015 issued on 13 July 2015.

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

The procedure started on 18 October 2016.

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 asthma

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

- Treatment of persistent asthma in paediatric patients 6 to less than 18 years of age that is inadequately controlled with medium to high doses of inhaled corticosteroids and a second controller medication
- Treatment of children 6 months to less than 6 years of age with recurrent severe asthmatic wheezing uncontrolled by inhaled corticosteroids

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 measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate strength / presentation for children below 3 years of age.
Non-clinical studies		Not applicable.
Clinical studies	8	**Study 2** Open-label study to characterize the safety and pharmacokinetics (PK) of a single administration of dupilumab in paediatric patients 6 years to less than 18 years of age.

		Study 3 Randomized, double-blind, placebo controlled, parallel group study to assess the efficacy and long term safety of dupilumab in adolescent (and in adult) patients with inadequately controlled asthma. **Study 4 removed during procedure EMEA-001501-PIP02-M01** **Study 5** Study to evaluate the Safety, Pharmacokinetics (PK) and Efficacy of dupilumab in patients, 6 months to less than 6 years of age, with severe Atopic Dermatitis (AD).. **Study 6** Randomized, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in children 6 to less than 12 years old with persistent uncontrolled asthma. **Study 7** Randomized, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in children 6 months to less than 6 years old with recurrent severe asthmatic wheezing uncontrolled by inhaled corticosteroids. **Study 8** Open-label follow-up study to evaluate the long-term safety and tolerability of dupilumab in adolescent (and in adult) patients who participated in previous dupilumab asthma clinical studies. **Study 9** Open-label follow-up study to evaluate the long-term safety and tolerability of dupilumab in children 6 months to less than 12 years patients who participated in previous dupilumab asthma clinical studies.
Extrapolation, modelling and simulation studies	1	**Study 10** Modelling and simulation study to determinate the appropriate dose /regimen for the efficacy and safety studies in children 6 months to less than 18 years of age.
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 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes