EMA/585817/2010

European Medicines Agency decision

P/187/2010

of 24 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant human monoclonal antibody to human interleukin-13, (EMEA-000782-PIP01-09) 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 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 application submitted by MedImmune Ltd on 11 December 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 August 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting of a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for recombinant human monoclonal antibody to human interleukin-13, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for recombinant human monoclonal antibody to human interleukin-13, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for recombinant human monoclonal antibody to human interleukin-13, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to MedImmune Ltd, Milstein Building, Granta Park, CB216GH, Cambridge, United Kingdom.

Done at London, 24 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/358781/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000782-PIP01-09

Scope of the application

Active substance(s):

Recombinant human monoclonal antibody to human interleukin-13

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

MedImmune Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MedImmune Ltd submitted for agreement to the European Medicines Agency on 11 December 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 January 2009.

Supplementary information was provided by the applicant on 28 May 2010.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - To agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member(s) do agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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(es) and appendix.

London, 6 August 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Treatment of asthma

2. Waiver

2.1. Condition

Treatment of asthma

The waiver applies to:

- the paediatric population from birth to less than 6 years of age,
- for solution for injection, subcutaneous use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Treatment of asthma

3.1.1. Indication targeted by the PIP

Treatment of uncontrolled asthma despite the daily use of medium or high dose inhaled corticosteroid and long-acting beta-2-agonist.

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

From 6 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Solution for injection

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	6	1. Single-dose, open-label, parallel-group study to evaluate the safety, tolerability, and pharmacokinetics (PK) of subcutaneous (SC) CAT-354 in adolescents (12 to less than 18 years) and adults with uncontrolled

Area	Number of studies	Description
		asthma. 2. Multicentre, randomised, double blind, placebo controlled, add-on study to standard therapy to evaluate the efficacy and safety of subcutaneous CAT-354 in adults and adolescent subjects with uncontrolled asthma. 3. Multicentre, randomised double blind placebo controlled add-on study to standard therapy to evaluate the efficacy and safety of subcutaneous CAT-354 in adults and adolescent subjects with uncontrolled asthma. 4. Open label, single ascending-dose study to evaluate the safety, tolerability, efficacy, PK and immunogenicity of subcutaneous CAT-354 in children (6 to less than 12 years) with uncontrolled asthma. 5. Multicentre, randomised, double-blind, placebo controlled, parallel-arm, dose-ranging add-on study to standard therapy to evaluate the efficacy and safety of CAT-354 in children aged 6 to less than 12 years with uncontrolled asthma and determine an appropriate dose for the subsequent pivotal study in children 6 to less than 12 years. 6. Multicentre, randomised double blind placebo controlled add-on study to standard therapy in order to evaluate the efficacy and safety of subcutaneous CAT-354 in children aged 6 to less than 12 years with uncontrolled asthma.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes