

EMA/248952/2013

European Medicines Agency decision

P/0126/2013

of 28 May 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for benralizumab (EMA-001214-PIP01-11) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by MedImmune Ltd on 7 November 2011 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 12 April 2013, 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 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 benralizumab, solution for injection (in pre-filled syringe), 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 benralizumab, solution for injection (in pre-filled syringe), 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 benralizumab, solution for injection (in pre-filled syringe), 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, 28 May 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/41207/2013

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

EMA-001214-PIP01-11

Scope of the application

Active substance(s):

Benralizumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection (in pre-filled syringe)

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 7 November 2011 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 14 December 2011.

Supplementary information was provided by the applicant on 18 January 2013. The applicant proposed modifications to the paediatric investigation plan.

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 Icelandic and the Norwegian Paediatric Committee members agree 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 and appendix.

London, 12 April 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

Waiver

1.1. Condition: treatment of asthma

The waiver applies to:

- the paediatric population from birth to less than 5 years;
- for solution for injection (in pre-filled syringe), 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 asthma

2.1.1. Indication(s) targeted by the PIP

Treatment of children and adolescents (5-17 years) whose eosinophilic, persistent asthma is inadequately controlled with medium- to high-dose ICS plus at least one additional controller medication.

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

From 5 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection (in pre-filled syringe)

2.1.4. Measures

Area	Number of measures	Description
Quality		Not applicable. Should the dosing strategy be changed to mg/kg bodyweight, the proposed presentation must be agreed by the PDCO to ensure that the formulation is able to cover the full range of paediatric doses and that the delivering device can ensure accuracy of all the doses.
Non-clinical		Not applicable.
Clinical	7	1. Multicentre, randomized, double-blind, placebo-controlled 48-week study to evaluate the efficacy and safety of subcutaneous (SC) benralizumab (MEDI-563) in adolescent (and adult) subjects with uncontrolled asthma. 2. Multicentre, randomized, double-blind, placebo-controlled 48-week study to evaluate the efficacy and safety of subcutaneous (SC) benralizumab (MEDI-563) in adolescent (and adult) subjects with uncontrolled asthma.

Area	Number of measures	Description
		3. Open-label, single ascending-dose study to evaluate the PK, safety, and tolerability of SC benralizumab in children 5-11 years with asthma. 4. Multicentre, randomized, double-blind, placebo-controlled 48-week dose range finding study in children aged 5-11 years with uncontrolled asthma. 5. Multicentre, randomized, double-blind, placebo-controlled 48-week study to evaluate the efficacy and safety of SC benralizumab in children aged 5-11 years with uncontrolled eosinophilic asthma. 6. Multicentre, 2-year extension study to evaluate the efficacy and safety of subcutaneous benralizumab in adolescent (and adult subjects) with inadequately controlled asthma. 7. Multicentre, 2-year extension study to evaluate the efficacy and safety of subcutaneous benralizumab in children with inadequately controlled asthma.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes