EMA/738870/2013

European Medicines Agency decision

P/0020/2014

of 22 January 2014

on the acceptance of a modification of an agreed paediatric investigation plan for benralizumab (EMEA-001214-PIP01-11-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 benralizumab (EMEA-001214-PIP01-11-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/0126/2013 issued on 28 May 2013,

Having regard to the application submitted by MedImmune Ltd on 13 September 2013 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 6 December 2013, 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 benralizumab, solution for injection, subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee

Article 2

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

Done at London, 22 January 2014

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

EMA/PDCO/577182/2013

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

EMEA-001214-PIP01-11-M01

Scope of the application

Active substance(s):

Benralizumab

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 22 of Regulation (EC) No 1901/2006 as amended, MedImmune Ltd submitted to the European Medicines Agency on 13 September 2013 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/0126/2013 issued on 28 May 2013.

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

The procedure started on 10 October 2013.

Scope of the modification

Some measures 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.

London, 6 December 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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

1. 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, 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 to less than 18 years) whose eosinophilic persistent asthma is inadequately controlled with medium-dose to high-dose inhaled corticosteroids (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		Development of an age appropriate presentation (solution for injection in pre-filled syringe) to ensure that the formulation is able to cover the full range of paediatric doses.
Non-clinical		Not applicable.
Clinical	8	1. Multicentre, randomized, double-blind, placebo-controlled 56-week study to evaluate the efficacy and safety of subcutaneous (SC) benralizumab (MEDI-563) in adolescents (and adults) 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 adolescents (and adults) with uncontrolled asthma. 3. Open-label, single ascending-dose study to evaluate the PK, safety, and tolerability of SC benralizumab in children 5 to less than 12 years with asthma.

Area	Number of measures	Description
		4. Multicentre, randomized, double-blind, placebo-controlled 48-week dose range finding study in children aged 5 to less than 12 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 to less than 12 years with uncontrolled eosinophilic asthma. 6. Multicentre, double-blind, active treatment extension study to establish the long-term safety of two dosing regimens 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. 8. Multicentre, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, population PK and immunogenicity of subcutaneous (SC) benralizumab (MEDI-563) in adolescents (and adults) with uncontrolled 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