EMA/151867/2018

European Medicines Agency decision

P/0107/2018

of 11 April 2018

on the acceptance of a modification of an agreed paediatric investigation plan for benralizumab (Fasenra), (EMEA-001214-PIP01-11-M07) 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 European Medicines Agency's decision P/0126/2013 issued on 28 May 2013, the decision P/0020/2014 issued on 22 January 2014, the decision P/0018/2015 issued on 30 January 2015, the decision P/0146/2015 issued on 10 July 2015, the decision P/0283/2015 issued on 27 November 2015 and the decision P/0213/2016 issued on 12 August 2016,

Having regard to the application submitted by AstraZeneca AB on 11 December 2017 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 23 February 2018, 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 waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for benralizumab (Fasenra), solution for injection, subcutaneous use, including changes to the waiver, 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 AstraZeneca AB, Södertälje, SE-151 85 – Södertälje, Sweden.

EMA/PDCO/829017/2017
London, 23 February 2018

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

EMEA-001214-PIP01-11-M07

Scope of the application

Active substance(s):

Benralizumab

Invented name:

Fasenra

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 11 December 2017 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 decision P/0020/2014 issued on 22 January 2014, the decision P/0018/2015 issued on 30 January 2015, the decision P/0146/2015 issued on 10 July 2015, the decision P/0283/2015 issued on 27 November 2015 and the decision P/0213/2016 issued on 12 August 2016.

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

The procedure started on 3 January 2018.

Scope of the modification

A waiver for a new paediatric subset has been added.

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 waiver 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 annexes 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 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

Add on treatment for uncontrolled asthma with eosinophilic inflammation in children 6 years and older, adolescents (and adults)

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

From 6 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-related studies	1	**Study 1** 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 studies	0	Not applicable.
Clinical studies	8	**Study 2** 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.

		Study 3 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. **Study 4** Open-label, single ascending-dose study to evaluate the PK, safety, and tolerability of SC benralizumab in children 6 to less than 12 years with asthma. **Study 5** Multicentre, randomized, double-blind, placebo-controlled 48-week dose range finding study in children aged 6 to less than 12 years with uncontrolled asthma. **Study 6** Multicentre, randomized, double-blind, placebo-controlled 48-week study to evaluate the efficacy and safety of SC benralizumab in children aged 6 to less than 12 years with uncontrolled eosinophilic asthma. **Study 7** Randomized, parallel group extension study to establish the long-term safety of two dosing regimens of subcutaneous benralizumab in adolescent (and adult) subjects with inadequately controlled asthma. **Study 8** Multicentre, 2-year extension study to evaluate the efficacy and safety of subcutaneous benralizumab in children with inadequately controlled asthma. **Study 9** (added in procedure EMEA-001214-PIP01-11-M04) Multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the effect of benralizumab on immune responses following seasonal influenza virus vaccination in adolescent patients (and young adults) with asthma.
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 April 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indication(s):

- add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use