



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/171103/2023

European Medicines Agency decision P/0173/2023

of 15 May 2023

on the acceptance of a modification of an agreed paediatric investigation plan for benralizumab (Fasenra), (EMA-001214-PIP09-21-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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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0225/2022 issued on 8 July 2022,

Having regard to the application submitted by AstraZeneca AB on 16 December 2022 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 31 March 2023, 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, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for benralizumab (Fasenra), solution for injection, subcutaneous use, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0126/2013 issued on 28 May 2013, including subsequent modifications thereof.

Article 3

This decision is addressed to AstraZeneca AB, Södertälje, SE-151 85 – Södertälje, Sweden.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/3883/2023
Amsterdam, 31 March 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001214-PIP09-21-M01

Scope of the application

Active substance(s):

Benralizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of eosinophilic granulomatosis with polyangiitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 16 December 2022 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/0225/2022 issued on 8 July 2022.

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

The procedure started on 30 January 2023.



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 in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway 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 eosinophilic granulomatosis with polyangiitis (EGPA)

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

2.1.1. Indication(s) targeted by the PIP

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

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

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of an age-appropriate presentation (solution for injection in pre-filled syringe) suitable for children from 6 years of age.
Non-clinical studies	Not applicable.
Clinical studies	Study 2 Open-label, uncontrolled trial to evaluate safety, pharmacokinetics (PK), pharmacodynamics (PD), activity and immunogenicity of benralizumab in children from 6 years to less than 18 years of age with EGPA, plus paediatric patients with other eosinophilic diseases.

Extrapolation, modelling and simulation studies	<p>Study 3</p> <p>Modelling & simulation study to evaluate benralizumab use in children from 6 years to less than 18 years of age with EGPA, plus paediatric patients with other eosinophilic diseases (CLIPS).</p> <p>Study 4</p> <p>Extrapolation study in children and adolescents with EGPA from 6 years to less than 18 years of age based on population pharmacokinetics (PK) and population PK/pharmacodynamics (PD) models and clinical data.</p>
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:	No
Date of completion of the paediatric investigation plan:	By June 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):

- Fasenra is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β -agonists.
 - Invented name(s): Fasenra
 - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe (injection), Solution for injection in pre-filled pen (injection) (Fasenra Pen)
 - Authorised route(s) of administration: Subcutaneous use
 - Authorised via centralised procedure