EMA/320727/2024

European Medicines Agency decision

P/0307/2024

of 16 August 2024

on the acceptance of a modification of an agreed paediatric investigation plan for benralizumab (Fasenra), (EMEA-001214-PIP04-19-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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0035/2022 issued on 31 January 2022,

Having regard to the application submitted by AstraZeneca AB on 22 March 2024 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 28 June 2024, 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 deferral.

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

[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, solution for injection/infusion, subcutaneous use, including changes to the deferral, 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.

EMA/PDCO/141565/2024
Amsterdam, 28 June 2024

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

EMEA-001214-PIP04-19-M01

Scope of the application

Active substance(s):

Benralizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypereosinophilic syndrome

Pharmaceutical form(s):

Solution for injection

Solution for injection/infusion

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 22 March 2024 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/0035/2022 issued on 31 January 2022.

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

The procedure started on 29 April 2024.

Scope of the modification

Some measures of the Paediatric Investigation Plan and the deferral 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 and to the deferral 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 hypereosinophilic syndrome (HES)

The waiver applies to:

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

2. Paediatric investigation plan

2.1. Condition:

Treatment of hypereosinophilic syndrome (HES)

2.1.1. Indication(s) targeted by the PIP

Treatment of hypereosinophilic syndrome (HES)

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

Solution for injection/infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1 (NATRON)** Randomised, placebo-controlled, double-blind, parallel-group, multicentre, study to evaluate the efficacy and safety of benralizumab in adolescents from 12 years to less than 18 years of age (and adults) with symptomatic active HES who were determined as responsive to oral corticosteroid treatment.

		Study 2 (CLIPS) Open-label study to evaluate the long-term safety, pharmacokinetics (PK), pharmacodynamics (PD), and immunogenicity of benralizumab in children aged from 6 years to less than 12 years of age with a documented diagnosis of HES (in addition to children with other eosinophilic diseases).
Extrapolation, modelling and simulation studies	2	**Study 3** Modelling and simulation study to evaluate the use of the product in children from 6 years to less than 12 years of age with HES (and other eosinophilic diseases). **Study 4** Partial extrapolation study based on population pharmacokinetics (PK) and population PK/pharmacodynamics (PD) models and clinical data from adults/ adolescents with HES (source population) to children with HES aged 6 years to < 12 years (target population).
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:	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

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of eosinophilic asthma

Authorised indication(s):

- 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
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure