EMA/8977/2022

# European Medicines Agency decision

P/0035/2022

of 31 January 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for benralizumab (Fasenra), (EMEA-001214-PIP04-19) 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 application submitted by AstraZeneca AB on 12 July 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 December 2021, in accordance with Article 17 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

A paediatric investigation plan for benralizumab (Fasenra), solution for injection, solution for injection/infusion, 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 (Fasenra), solution for injection, solution for injection/infusion, 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 (Fasenra), solution for injection, solution for injection/infusion, 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 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.

***Article 5***

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

EMA/PDCO/545780/2021
Amsterdam, 17 December 2021

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

EMEA-001214-PIP04-19

## Scope of the application

**Active substance(s):**

Benralizumab

**Invented name:**

Fasenra

**Condition(s):**

Treatment of hypereosinophilic syndrome

**Authorised indication(s):**

See Annex II

**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

**Information about the authorised medicinal product:**

See Annex II

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 12 July 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 20 August 2019.

Supplementary information was provided by the applicant on 10 September 2021. The applicant proposed modifications to the paediatric investigation plan and requested a waiver.

## 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 17(1) 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 Norwegian Paediatric Committee member agrees 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 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)**<br>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)**<br><br>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**<br><br>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).<br><br>**Study 4**<br><br>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 2028 |
| 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 eosinophilic 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

## Authorised pharmaceutical form(s):

Solution for injection in pre-filled syringe

## Authorised route(s) of administration:

Subcutaneous use