EMA/12076/2022

European Medicines Agency decision

P/0038/2022

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-PIP07-21) 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.

European Medicines Agency decision

P/0038/2022

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-PIP07-21) 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 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 16 April 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 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, age-appropriate dosage form for parenteral use, 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, age-appropriate dosage form for parenteral use, 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, age-appropriate dosage form for parenteral use, 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, the decision P/0288/2017 issued on 4 October 2017, the decision P/0388/2021 issued on 8 September 2021, the decision P/0314/2020 issued on 14 August 2020, the decision P/0497/2021 issued on 3 December 2021, the decision P/0035/2022 issued on 31 January 2022, including subsequent modifications thereof.

Article 5

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

EMA/PDCO/545885/2021
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-PIP07-21

Scope of the application

Active substance(s):

Benralizumab

Invented name:

Fasenra

Condition(s):

Treatment of eosinophilic gastritis/gastroenteritis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Solution for injection/infusion

Age-appropriate dosage form for parenteral use

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 16 April 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 25 May 2021.

Supplementary information was provided by the applicant on 9 September 2021. The applicant proposed modifications to the paediatric investigation plan.

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 eosinophilic gastritis/gastroenteritis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for injection, solution for injection/infusion, age-appropriate dosage form for parenteral use, subcutaneous use, intravenous 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 eosinophilic gastritis/gastroenteritis

2.1.1. Indication(s) targeted by the PIP

Treatment of eosinophilic gastritis/gastroenteritis

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

Solution for injection/infusion

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of appropriate dosage form and formulation to enable weight-based dosing in patients younger than 6 years of age weighing less than 15 kg
Non-clinical studies	0	Not applicable

Clinical studies	2	**Study 2 (D3258C00001)** Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of benralizumab in adolescents from 12 years to less than 18 years of age (and adults) with eosinophilic gastritis/gastroenteritis (EG/EGE) **Study 3 (CLIPS)** Open-label, non-comparative trial to evaluate pharmacokinetics, pharmacodynamics, safety and immunogenicity of benralizumab in children from 2 years to less than 12 years of age with eosinophilic gastritis/gastroenteritis (EG/EGE) or other eosinophilic diseases
Extrapolation, modelling and simulation studies	1	**Study 4** Modelling and simulation study (population pharmacokinetics/pharmacodynamics) to project the concentration-time profiles of benralizumab and the dynamics of blood eosinophils in children from 2 years to less than 12 years of age with eosinophilic gastritis/gastroenteritis
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 2027
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

Authorised route(s) of administration:

Subcutaneous use