EMA/463911/2021

European Medicines Agency decision

P/0372/2021

of 8 September 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for ligelizumab (EMEA-001811-PIP03-20) 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 application submitted by Novartis Europharm Limited on 25 November 2020 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 23 July 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for ligelizumab, solution for injection, 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 ligelizumab, solution for injection, 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 ligelizumab, solution for injection, 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 is addressed to Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, D04A9N6 – Dublin, Ireland.

EMA/PDCO/256192/2021 Corr
Amsterdam, 23 July 2021

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

EMEA-001811-PIP03-20

Scope of the application

Active substance(s):

Ligelizumab

Condition(s):

Treatment of food allergy

Pharmaceutical form(s):

Solution for injection

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 25 November 2020 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 4 January 2021.

Supplementary information was provided by the applicant on 16 April 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 annex 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 food allergy

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution for injection, age-appropriate dosage form for parenteral use, 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 food allergy

2.1.1. Indication(s) targeted by the PIP

Prevention of allergic reactions, including anaphylaxis, following accidental exposure to food allergens in adolescents and paediatric patients 6 months of age and older with a confirmed diagnosis of IgE driven food allergy to one or more allergens

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

Age-appropriate dosage form for parenteral use

2.1.4. Age-appropriate dosage form for parenteral use Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate strength of solution for injection for children from 6 months to less than 6 years of age
Non-clinical studies	0	Not applicable.

Area	Number of measures	Description
Clinical studies	3	**Study 2** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of ligelizumab in children from 6 years to less than 18 years of age (and adults) with peanut allergy (CQGE031G12301 peanut pivotal study) **Study 3** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of ligelizumab in children from 6 years to less than 18 years of age (and adults) with milk or egg allergy (CQGE031G12302 milk and egg pivotal basket study) **Study 4** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of ligelizumab in children from 6 months to less than 6 years of age with peanut, milk or egg allergy (CQGE031H12301 food allergies paediatric study 6mo-6y)
Extrapolation, modelling and simulation studies	1	**Study 5** Modelling and simulation study to characterize the dose-exposure oral food challenge response in patients 6 years of age and above and then extrapolate the PK/PD in children from 6 months to less than 6 years of age with peanut, milk or egg allergy to select the appropriate dose in Study 4 CQGE031H12301 (Modelling and Simulation Activity 3 + 3b)
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 June 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes