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European Medicines Agency decision

P/0329/2017

of 30 October 2017

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-PIP02-15) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

An agency of the European Union

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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 Ltd. on 9 September 2016 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 15 September 2017, in accordance with Article 18 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 Ltd., Frimley Business Park, GU16 7SR – Camberley, United Kingdom.

EMA/PDCO/407199/2017
London, 15 September 2017

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

EMEA-001811-PIP02-15

Scope of the application

Active substance(s):

Ligelizumab

Condition(s):

Treatment of chronic spontaneous urticaria

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 Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted for agreement to the European Medicines Agency on 9 September 2016 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 18 October 2016.

Supplementary information was provided by the applicant on 23 June 2017. 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 18 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 chronic spontaneous urticaria

The waiver applies to:

- all subsets of the paediatric population from birth to less than 2 years of age;
- solution for injection and age-appropriate dosage form, 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 chronic spontaneous urticaria

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic spontaneous urticaria, with or without angioedema in patients with an inadequate response to H1-antihistamine treatment

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

From 2 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. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an appropriate strength of solution for injection for the paediatric population from 2 to less than 12 years of age
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 2** Double-blind, randomised, placebo-controlled, parallel-group trial to evaluate pharmacokinetics, safety and activity of ligelizumab in children from 12 to less than 18 years of age with chronic spontaneous urticaria

		Study 3 Double-blind, randomised, active-controlled, parallel-group trial to evaluate efficacy and safety of ligelizumab in children from 12 to less than 18 years of age with chronic spontaneous urticaria **Study 4** Open-label, uncontrolled trial to evaluate pharmacokinetics, safety and activity of ligelizumab in children from 2 to less than 12 years of age with chronic spontaneous urticaria
Extrapolation, modelling and simulation studies	4	**Study 5** Modelling and simulation study to establish the dose of ligelizumab in Study 2 **Study 6** Modelling and simulation study to establish the dose of ligelizumab in Study 3 and Study 4 **Study 7** Modelling and simulation study to establish the dose of ligelizumab in children from 2 to less than 6 years of age in Study 4 **Study 8** Extrapolation analysis of existing PK/PD data on ligelizumab on chronic spontaneous urticaria
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 October 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes