EMA/299993/2020

European Medicines Agency decision

P/0208/2020

of 16 June 2020

on the acceptance of a modification of an agreed paediatric investigation plan for ligelizumab (EMEA-001811-PIP02-15-M03) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

P/0208/2020

of 16 June 2020

on the acceptance of a modification of an agreed paediatric investigation plan for ligelizumab (EMEA-001811-PIP02-15-M03) 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 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 European Medicines Agency's decision P/0329/2017 issued on 30 October 2017 and the decision P/0221/2018 issued on 17 July 2018,

Having regard to the application submitted by Novartis Europharm Limited on 27 January 2020 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 30 April 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for ligelizumab, solution for injection, age-appropriate dosage form, parenteral 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 is addressed to Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, D04A9N6 - Dublin, Ireland.

EMA/PDCO/72784/2020
Amsterdam, 30 April 2020

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

EMEA-001811-PIP02-15-M03

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 Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 27 January 2020 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/0329/2017 issued on 30 October 2017 and the decision P/0221/2018 issued on 17 July 2018.

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

The procedure started on 2 March 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan 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 Norwegian Paediatric Committee member 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 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 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	4	**Study 2 (CQGE031C2202)** 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** *Deleted during procedure EMEA-001811-PIP02-15-M02* **Study 4 (CQGE031C2305)** 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 **Study 9 (CQGE031C2302)** *Added during procedure EMEA-001811-PIP02-15-M02* Double-blind, randomised, active and placebo-controlled, parallel-group trial to evaluate efficacy and safety of ligelizumab in children from 12 to less than 18 years of age (and adults) with chronic spontaneous urticaria **Study 10 (CQGE031C2303)** *Added during procedure EMEA-001811-PIP02-15-M02* Double-blind, randomised, active and placebo-controlled, parallel-group trial to evaluate efficacy and safety of ligelizumab in children from 12 to less than 18 years of age (and adults) with chronic spontaneous urticaria
Extrapolation, modelling and simulation studies	5	**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 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 (children from 2 to less than 12 years of age) **Study 11** Extrapolation analysis of existing PK/PD adolescent 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 August 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes