



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/776144/2014

European Medicines Agency decision

P/0017/2015

of 30 January 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for reslizumab (EMEA-001202-PIP02-13) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Teva Pharma GmbH on 13 December 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 December 2014, 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 reslizumab, concentrate for solution for infusion, solution for injection, intravenous 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 reslizumab, concentrate for solution for infusion, solution for injection, intravenous 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 reslizumab, concentrate for solution for infusion, solution for injection, intravenous 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 Teva Pharma GmbH, Waldeckerstr. 7, 64546 - Mörfelden-Walldorf, Germany.

Done at London, 30 January 2015

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/585946/2014

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

EMA-001202-PIP02-13

Scope of the application

Active substance(s):

Reslizumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name / corporate name of the PIP applicant:

Teva Pharma GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Teva Pharma GmbH submitted for agreement to the European Medicines Agency on 13 December 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 26 February 2014.

Supplementary information was provided by the applicant on 22 September 2014. The applicant proposed modifications to the paediatric investigation plan and requested a deferral.



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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 12 December 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 asthma

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- for concentrate for solution for infusion for intravenous use, and for solution for injection for subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Add-on treatment to reduce exacerbations, relieve symptoms and improve lung function in paediatric patients from 6 to less than 18 years of age with inadequately controlled moderate to severe asthma who have a blood eosinophil count $\geq 400/\mu\text{L}$

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of solution for injection for subcutaneous use appropriate for the paediatric population from 6 years of age
Non-clinical studies	0	Not applicable

Clinical studies	3	Study 2: Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of reslizumab as add-on to best standard of care in children from 12 to less than 18 years of age (and in adults) with uncontrolled moderate to severe asthma Study 3: Open-label, parallel group trial to evaluate pharmacokinetics and activity of reslizumab in children from 6 to less than 12 years of age with uncontrolled asthma Study 4: Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of reslizumab as add-on to best standard of care in children from 6 to less than 12 years of age with uncontrolled moderate to severe asthma
Extrapolation, modelling and simulation studies	3	Study 5: Modelling and simulation study to support the dose selection of SC reslizumab for the single dose PK/PD study in paediatric patients with asthma (Study 3) Study 6: Modelling and simulation study to support SC reslizumab dose selection for the Phase 3 study in paediatric patients with eosinophilic asthma (Study 4) Study 7: Modelling and simulation study to support the registration of SC reslizumab for paediatric patients with eosinophilic asthma
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 March 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes