EMA/585769/2016

European Medicines Agency decision

P/0256/2016

of 5 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for reslizumab (EMEA-001202-PIP02-13-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for reslizumab (EMEA-001202-PIP02-13-M01) 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/0017/2015 issued on 30 January 2015,

Having regard to the application submitted by Teva Pharmaceuticals Europe on 30 May 2016 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 19 August 2016, 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 reslizumab, concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous 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 Teva Pharmaceuticals Europe, Field House, Station Approach, CM20 2FB – Harlow, United Kingdom.

EMA/PDCO/377317/2016
London, 19 August 2016

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

EMEA-001202-PIP02-13-M01

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 Pharmaceuticals Europe

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva Pharmaceuticals Europe submitted to the European Medicines Agency on 30 May 2016 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/0017/2015 issued on 30 January 2015.

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

The procedure started on 21 June 2016.

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 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 ≥ 300/µL

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 the safety and efficacy of reslizumab as add-on to best standard of care in adolescents from 12 to less than 18 years of age (and in adults) with uncontrolled moderate to severe asthma and elevated blood eosinophils **Study 3** Open-label, randomised parallel group trial to evaluate the pharmacokinetics, pharmacodynamics, immunogenicity, safety and tolerability 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 the 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 severe asthma and elevated blood eosinophils
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 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes