

EMA/688239/2015

European Medicines Agency decision

P/0281/2015

of 27 November 2015

on the acceptance of a modification of an agreed paediatric investigation plan for lebrikizumab (EMA-001053-PIP01-10-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.

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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 European Medicines Agency's decision P/0011/2012 issued on 24 January 2012, the decision P/0279/2012 issued on 21 November 2012, and the decision P/0258/2013 issued on 29 October 2013,

Having regard to the application submitted by Roche Product Limited on 20 July 2015 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 9 October 2015, 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.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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 lebrikizumab, solution for injection, subcutaneous use, 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 Roche Product Limited, 6 Falcon Way, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 27 November 2015

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

EMA/PDCO/514660/2015
London, 9 October 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001053-PIP01-10-M03

Scope of the application

Active substance(s):

Lebrikizumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

Roche Product Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Product Limited submitted to the European Medicines Agency on 20 July 2015 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/0011/2012 issued on 24 January 2012, the decision P/0279/2012 issued on 21 November 2012, and the decision P/0258/2013 issued on 29 October 2013.

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

The procedure started on 11 August 2015.

Scope of the modification

Some measures 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 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:

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

2. Paediatric Investigation Plan

2.1.1. Condition:

Treatment of asthma

2.1.2. Indication(s) targeted by the PIP

Treatment of asthma uncontrolled with inhaled corticosteroid and a second controller agent

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

From 6 to less than 18 years of age

2.1.4. Pharmaceutical form(s)

Solution for injection

2.1.5. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	2	Study 1 8-month male fertility study in monkeys. Study 2 10-month developmental and peri-/postnatal study in monkeys.
Clinical studies	3	Study 3 Double-blind, randomised, multiple-dose, placebo-controlled parallel-group trial to evaluate efficacy, safety and tolerability of lebrikizumab in children from 12 to less than 18 years of

		age with asthma. Study 4 Double-blind, randomised, placebo-controlled parallel-group trial to evaluate efficacy (oral corticosteroid sparing effect) of lebrikizumab in children from 12 to less than 18 years of age (and in adults) with asthma. Study 5 Double-blind, randomised, multiple-dose, placebo-controlled parallel-group trial to evaluate efficacy, safety and tolerability of lebrikizumab in children from 6 to less than 12 years of age with asthma.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 January 2024
Deferral for one or more studies contained in the paediatric investigation plan:	Yes