EMA/666041/2017

European Medicines Agency decision

P/0321/2017

of 31 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tralokinumab (EMEA-000782-PIP01-09-M04) 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 tralokinumab (EMEA-000782-PIP01-09-M04) 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/187/2010 issued on 24 September 2010, the decision P/280/2011 issued on 28 November 2011, the decision P/0198/2014 issued on 8 August 2014, and the decision P/0099/2016 issued on 15 April 2016,

Having regard to the application submitted by MedImmune Ltd on 26 June 2017 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 15 September 2017, 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 tralokinumab, 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 MedImmune Ltd, Milstein Building, Granta Park, CB216GH – Cambridge, United Kingdom.

EMA/PDCO/422273/2017
London, 15 September 2017

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

EMEA-000782-PIP01-09-M04

Scope of the application

Active substance(s):

Tralokinumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

MedImmune Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, MedImmune Ltd submitted to the European Medicines Agency on 26 June 2017 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/187/2010 issued on 24 September 2010, the decision P/280/2011 issued on 28 November 2011, the decision P/0198/2014 issued on 8 August 2014, and the decision P/0099/2016 issued on 15 April 2016.

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

The procedure started on 18 July 2017.

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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:

- the paediatric population from birth to less than 5 years of age;
- 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. Condition to be investigated: treatment of asthma

2.1.1. Indication targeted by the PIP

Treatment of uncontrolled asthma despite the daily use of medium or high dose inhaled corticosteroid and long-acting beta-2-agonist.

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

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	6	**Study 1** Single-dose, open-label study to evaluate the safety, tolerability, and pharmacokinetics (PK) of subcutaneous (SC) CAT-354 in adolescents (12 to less than 18 years) with asthma. **Study 2** Multicentre, randomised, double blind, placebo controlled, add-on study to standard therapy to evaluate the efficacy and safety of subcutaneous CAT-354 in adults and adolescent subjects with uncontrolled asthma.

		Study 3 Multicentre, randomised double blind placebo controlled add-on study to standard therapy to evaluate the efficacy and safety of subcutaneous CAT-354 in adults and adolescent subjects with uncontrolled asthma. **Study 4** Randomised, double-blind, placebo controlled, parallel group study to evaluate the efficacy and safety of tralokinumab in reducing oral corticosteroid (OCS) use in adolescents (and adults) with OCS-dependent asthma. **Study 5** Deleted in procedure EMEA-000782-PIP01-09-M03. **Study 6** Multicentre, randomised, double-blind, placebo controlled, parallel-arm, dose-ranging add-on study to standard therapy to evaluate the efficacy and safety of CAT-354 in children aged 5 to less than 12 years with uncontrolled asthma and determine an appropriate dose for the subsequent pivotal study in children 5 to less than 12 years. **Study 7** Multicentre, randomised double blind placebo controlled add-on study to standard therapy in order to evaluate the efficacy and safety of subcutaneous CAT-354 in children aged 5 to less than 12 years with uncontrolled asthma.
Extrapolation, modelling and simulation studies	2	**Study 8** Population PK/PD modelling and simulation study to support the reduced adolescent patient population in PIP Study 2 (D2210C00007) and Study 3 (D2210C00008). The PK model considered all clinical studies conducted to date with tralokinumab, including the PK data obtained in asthmatic adolescents. The PD model includes adult and adolescent data to characterize tralokinumab's dose-exposure-response (forced expiratory volume in one second, FEV1) after SC administration in asthmatic subjects. **Study 9** Partial extrapolation study for PK and PD data in the confirmatory trials of adolescent asthma patients (12-17 years) in order to support the reduced adolescent patient population in PIP Study 2 (D2210C00007) and Study 3 (D2210C00008), based on the population PK/PD modelling and simulation study (PIP study 7). Adolescent data obtained in confirmatory Phase 3 studies must be simulated in order to show consistency in treatment effect compared to adults and in order to corroborate the dose projections and the sample size.

Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2025
Deferral for one or more studies contained in the paediatric investigation plan:	Yes