EMA/474720/2019

European Medicines Agency decision

P/0328/2019

of 11 September 2019

on the acceptance of a modification of an agreed paediatric investigation plan for dermatophagoides pteronyssinus / dermatophagoides farinae (ACARIZAX and associated names), (EMEA-001258-PIP01-11-M05) 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 726/2004[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/0243/2012 issued on 22 October 2012, the decision P/0284/2015 issued on 27 November 2015 and the decision P/0056/2018 issued on 16 March 2018,

Having regard to the application submitted by ALK-Abelló A/S on 9 April 2019 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 26 July 2019, 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 and to the waiver.

(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 and to the 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

Changes to the agreed paediatric investigation plan for dermatophagoides pteronyssinus / dermatophagoides farinae (ACARIZAX and associated names), oral lyophilisate, sublingual use, including changes to the deferral and to the waiver, 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 ALK-Abelló A/S, Bøge Allé 6-8, 2970 – Hørsholm, Denmark.

EMA/PDCO/262108/2019 Corr

Amsterdam, 26 July 2019

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

EMEA-001258-PIP01-11-M05

Scope of the application

Active substance(s):

Dermatophagoides pteronyssinus / dermatophagoides farinae

Invented name:

ACARIZAX and associated names

Condition(s):

Treatment of asthma

Treatment of allergic rhinitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral lyophilisate

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

ALK-Abelló A/S

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ALK-Abelló A/S submitted to the European Medicines Agency on 9 April 2019 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/0243/2012 issued on 22 October 2012, the decision P/0284/2015 issued on 27 November 2015, and the decision P/0056/2018 issued on 16 March 2018.

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

The procedure started on 28 May 2019.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver 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 annexes 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 allergic rhinitis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- oral lyophilisate, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- the paediatric population from 12 to less than 18 years of age;
- oral lyophilisate, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.2. Condition

Treatment of asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- oral lyophilisate, sublingual 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 allergic rhinitis

2.1.1. Indication(s) targeted by the PIP

Treatment of allergic rhinitis due to house dust mites

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

From 5 to less than 12 years of age

2.1.3. Pharmaceutical form(s)

Oral lyophilisate

2.1.4. Studies

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	Study 1 (CDM trial) *Deleted during procedure EMEA-001258-PIP01-11-M05* Study 4 (MT-12) *Added during procedure EMEA-001258-PIP01-11-M05* Double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of the house dust mite (HDM) sublingual immunotherapy (SLIT) oral lyophilisate compared to placebo in children from 5 to less than 12 years of age with HDM-induced allergic rhinitis / rhinoconjunctivitis.

2.2. Condition

Treatment of asthma

2.2.1. Indication(s) targeted by the PIP

Treatment of allergic asthma due to house dust mites

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

From 5 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Oral lyophilisate

2.2.4. Studies

Area	Number of studies	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable

Clinical studies	1	*Study 2* *Deleted during procedure EMEA-001258-PIP01-11-M03* Study 3 *Added during procedure EMEA-001258-PIP01-11-M03* Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of the house dust mite (HDM) sublingual immunotherapy (SLIT) tablet compared to placebo in children from 5 to less than 18 years with HDM-induced allergic asthma

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2023
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of allergic rhinitis

Authorised indication(s):

- ACARIZAX is indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.
- ACARIZAX is indicated in adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.

2. Treatment of asthma

Authorised indication(s):

- ACARIZAX is indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment.

Authorised pharmaceutical form(s):

Oral lyophilisate

Authorised route(s) of administration:

Sublingual use