EMA/576895/2020

European Medicines Agency decision

P/0434/2020

of 6 November 2020

on the acceptance of a modification of an agreed paediatric investigation plan for birch pollen extract (*betula verrucosa*) (ITULAZAX), (EMEA-001879-PIP01-15-M02) 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/0302/2016 issued on 4 November 2016 and the decision P/0030/2018 issued on 30 January 2018,

Having regard to the application submitted by ALK-Abelló A/S on 1 July 2020 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 16 October 2020, 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 birch pollen extract (*betula verrucosa*) (ITULAZAX), oral lyophilisate, sublingual 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 ALK-Abelló A/S, Bøge Allé 6-8, 2970 – Hørsholm, Denmark.

EMA/PDCO/417757/2020
Amsterdam, 16 October 2020

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

EMEA-001879-PIP01-15-M02

Scope of the application

Active substance(s):

Birch pollen extract (*betula verrucosa*)

Invented name:

ITULAZAX

Condition(s):

Treatment of allergic rhinitis / rhino-conjunctivitis

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 1 July 2020 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/0302/2016 issued on 4 November 2016 and the decision P/0030/2018 issued on 30 January 2018.

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

The procedure started on 18 August 2020.

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 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 / rhino-conjunctivitis

The waiver applies to:

- 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 / rhino-conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of tree pollen allergic rhinitis / rhino-conjunctivitis

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)

Oral lyophilisate

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** (TT-04) Randomised, placebo-controlled, double-blind parallel-group trial to evaluate efficacy and safety of the SQ tree SLIT-tablet in adolescents (and adults) with allergic rhinitis /rhino-conjunctivitis due to birch pollen.

		Study 2 (TT-06) Randomised, placebo-controlled, double-blind parallel-group trial to evaluate efficacy and safety of the SQ tree SLIT-tablet in children 5 to less than 18 years of age with allergic rhinitis /rhino-conjunctivitis due to birch pollen.
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:	No
Date of completion of the paediatric investigation plan:	By September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of allergic rhinitis / rhino-conjunctivitis

Authorised indication(s):

- Treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group in adults.

Authorised pharmaceutical form(s):

Oral lyophilisate

Authorised route(s) of administration:

Sublingual use