



ALK's European registration application for ITULAZAX® for paediatric indication accepted for review

May 30, 2024

ALK (ALKB:DC / OMX: ALK B / AKBLF) today announced that the European regulatory filing for ITULAZAX® (tree sublingual allergy immunotherapy (SLIT) tablet) in young children has been accepted for review by the relevant health authorities. The European regulatory review process is anticipated to take up to nine months so that, subject to approval, the first market introductions in Europe could take place from the first half of 2025.

The data used in the European filing include results from a successfully completed Phase 3 clinical trial involving 952 children in Canada and Europe. The trial was a Phase 3, randomised, placebo-controlled trial to study the efficacy and safety of ITULAZAX® in children aged 5 to 17 with a clinical history of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from birch trees and other trees in the birch homologous group. The trial achieved its primary endpoint confirming an overall improvement of 22% compared to placebo. Results were highly statistically significant.

ALK's Executive Vice President of Research and Development, Henriette Mersebach, says: *"I'm pleased that our registration application for ITULAZAX® for young children has been accepted for review, and we look forward to the dialogue with the European authorities. The results in children are robust and consistent with previous trial results and this filing represents an important step forward for our ability to transform the medical treatment of children with tree pollen allergy as well as for ALK's long-term growth ambitions."*

Globally, it is estimated that more than 10 million children have uncontrolled respiratory allergies, and the number is growing. Tree pollen is a common cause of these uncontrolled allergies. In Europe, the ITULAZAX® tablet is currently approved for treatment of patients aged 18-65.

ALK-Abelló A/S

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About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,800 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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