ITULAZAX® tree pollen tablet approved for treatment of children in Europe

April 23, 2025

ALK (ALKB.DC / OMX: ALK B) today announced that its European regulatory filing for ITULAZAX® (tree pollen sublingual allergy immunotherapy tablet) for treatment of young children and adolescents aged five to 17 has been approved by the health authorities in 17 EU countries via a type II variation procedure. First market introductions are expected to follow in the coming months ahead of the 2025/2026 initiation season for new patients starting treatment on pollen allergy tablets.

Executive Vice President of R&D, Henriette Mersebach (MD), says: *"We are very pleased with the European health authorities' approval which allows us to provide this important treatment option to children and adolescents whose lives are impaired by uncontrolled tree pollen-induced respiratory allergy. Today's approval marks another significant milestone in our continuous efforts to make our respiratory tablets available to all age groups in all relevant markets".*

ALK's regulatory filing was based on data from the TT-06 clinical trial. TT-06 was a randomised, placebo-controlled Phase 3 trial involving 952 children and adolescents aged five 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 confirmed that the treatment was well tolerated and had a favourable safety profile. The peer-reviewed results were published in 2024 in the *European Journal of Allergy and Clinical Immunology*.

The tree tablet, branded ITULAZAX® in Europe and ITULATEK® in Canada, has, until now, been approved by 22 countries for adult patients aged 18 to 65. Corresponding paediatric regulatory reviews are currently ongoing in Canada, Switzerland, and the UK. These reviews are expected to complete in 2025.

The approval of ITULAZAX® for paediatric use marks the completion of ALK's decade-long development efforts, ensuring that five of the most common respiratory allergies (grass pollen, house dust mite, ragweed pollen, Japanese cedar pollen, and now tree pollen) are all covered by allergy immunotherapy tablets approved for children, adolescents, and adults in relevant markets.

The approval is not expected to affect ALK's financial outlook for 2025.

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About ALK
ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. ALK manufactures and markets allergy immunotherapy ('AIT') 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

- Company release 08 25UK 230425 Itulazax approval children