



ITULATEK® approved for treatment of children and adolescents in Canada

May 08, 2025

ALK (ALKB:DC / OMX: ALK B) today announced that Health Canada has approved ALK's regulatory filing for ITULATEK® (tree pollen sublingual allergy immunotherapy tablet) for treatment of children and adolescents aged five to 17. Accordingly, the tree pollen tablet is now indicated for treatment of moderate to severe seasonal allergic rhinitis, with or without conjunctivitis, induced by pollen from birch, alder, hazel, and/or oak, in children, adolescents, and adults five to 65 years of age in Canada.

Outside Europe, Canada is a key market for ALK's respiratory tablet portfolio demonstrating solid double-digit growth. The extended ITULATEK® label is expected to further support market expansion in Canada.

Executive Vice President of R&D, Henriette Mersebach (MD), says: *We appreciate the Canadian approval and look forward to offering this important treatment option to children and adolescents affected by uncontrolled tree pollen-induced respiratory allergy. The approval is yet another testament to our relentless pursuit of making our respiratory tablet portfolio available across markets and age groups".*

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 pollen tablet, branded ITULAZAX® in Europe and ITULATEK® in Canada, is currently approved by 22 countries for adult patients aged 18 to 65 and has recently been approved for treatment of children and adolescents aged five to 17 in 17 EU countries. Paediatric regulatory reviews are ongoing in Switzerland and the UK. These reviews are expected to complete in 2025.

With the extended label indications for ITULAZAX®/ITULATEK®, ALK has four tablets, covering 80% of the most prevalent respiratory allergies, approved for children, adolescents, and adults in Europe and Canada.

The approval does not affect ALK's financial guidance 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

- [InvestorNews_08May25_Itulatek_children_approval_in_Canada](#)