



ALK submits registration application for tree SLIT-tablet in Canada

June 24, 2019

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that the Canadian regulatory filing for its investigational tree pollen sublingual allergy immunotherapy (SLIT) tablet has been accepted for review by the relevant health authorities.

In Canada and Europe, the tree tablet will be a relevant treatment option for respiratory allergies caused by allergens from the birch homologous group of trees, which also includes alder, beech, hazel and oak.

The data used in the filing include results from the Phase III clinical trial finalised in 2017 with ALK's tree pollen SLIT-tablet in patients with birch pollen induced allergic rhinitis and/or conjunctivitis. Treatment with the tree SLIT-tablet reduced the total combined score (primary endpoint) by 40% compared to placebo. The effect was shown to be comparable across the entire birch, alder and hazel pollen season.

Henrik Jacobi, ALK's Executive Vice President, Research and Development, says: "We are confident that, if approved, this product will prove a valuable new treatment option to allergy specialists and tree pollen allergy sufferers in Canada. The effect seen in the clinical trial was among the most significant that we have ever seen in field studies of allergy immunotherapy."

ALK successfully completed the marketing authorisation procedure for its tree SLIT-tablet in Europe earlier this month and expects the product to become available in the first European markets in Germany and Scandinavia within this year.

This announcement does not impact ALK's financial guidance for 2019.

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 2,400 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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