ALK obtains European approval for its tree SLIT-tablet against allergic rhinitis

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that it has successfully completed the marketing authorisation procedure for its tree sublingual allergy immunotherapy (SLIT) tablet in 17 European countries. ITULAZAX® is expected to be the brand name of the tree SLIT-tablet.

Millions of Europeans suffer from tree pollen allergies. It is estimated that approximately 10% of allergic rhinitis sufferers have a condition which cannot be well controlled despite the use of symptom-relieving medication. For many of these patients, ITULAZAX® will be a relevant treatment option which can improve their quality of life by addressing the underlying cause of their disease and not just the symptoms.

ITULAZAX® is indicated in adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis, induced by pollen from the birch homologous family of trees, which also includes alder, beech, hazel, hornbeam and oak. ITULAZAX® is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).

Henrik Jacobi, Executive Vice President of R&D, ALK says: *"For the first time, patients in Europe will have access to an effective, well documented and fast-dissolving SLIT-tablet for tree pollen allergy with no special storage conditions and no updosing required. We are pleased that the registration procedure has been successfully completed in Europe less than a year after submission of the marketing authorisation application."*

He continues: *"This new home-based treatment option improves quality of life for patients with tree pollen allergic rhinitis that is not well controlled despite the use of symptom-relieving medications. Moreover, we are very pleased to see that the product was recognised by the authorities for its benefits across the whole tree pollen season."*

The data used in the filing were among the strongest pollen trial results ever seen in field studies of allergy immunotherapy. They include results from the Phase III clinical trial finalised in 2017 with ITULAZAX®. Treatment with ITULAZAX® 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.

Following today's completion of the registration procedure, ALK expects the product to become available in the first European markets in Germany and Scandinavia within this year, once national marketing authorisations and market access has been obtained. ITULAZAX® is the fourth ALK SLIT-tablet approved in Europe, including GRAZAX® (2006), ACARIZAX® (2015) and RAGWIZAX® (2017) covering the most common respiratory allergies treated with allergy immunotherapy globally.

ALK-Abelló A/S

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This information is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

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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