



Germany becomes first launch market for ALK's tree SLIT-tablet

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- ALK's new tree SLIT-tablet, ITULAZAX[®], has been launched in its first market: Germany
- Tree pollen allergy is highly prevalent in northern Europe, making Germany a key market for the product
- In trials, ITULAZAX[®] showed clinical benefits throughout the tree pollen season
- The launch marks another significant step towards ALK's strategy of commercialising tablets for five of the world's most important allergens

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) has confirmed the first launch of its sublingual allergy immunotherapy (SLIT) tablet for the treatment of tree pollen allergy. The product, branded ITULAZAX[®], was launched in Germany after ALK received national approval from authorities last month. This followed the successful completion of the marketing authorisation procedure in June for 17 European countries.

ITULAZAX[®] is a convenient, once-daily SLIT-tablet, which is well-tolerated and suitable for use at home. It is approved in Europe for use in patients aged 18-65 who have moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch-homologous family of trees – birch, alder, beech, hazel, hornbeam and oak – and whose symptoms cannot be adequately controlled with symptom-relieving medication.

Søren Niegel, ALK's Executive Vice President, Commercial Operations, said: "Tree pollen allergy is one of the world's major respiratory allergies. The launch of ITULAZAX[®] means that, for the first time, patients have access to a documented, registered sublingual tablet for their condition, which has shown unprecedented results in clinical trials. This launch is also a proud moment for ALK, as it marks a further step towards our strategic goal of commercialising tablets for five of the world's most important allergens – house dust mite, grass, tree, ragweed and Japanese cedar."

The clinical data submitted by ALK in support of its European marketing authorisation application included some of the strongest results ever seen by the company in allergy immunotherapy (AIT) trials. Results from a multi-national Phase III trial showed that treatment with ITULAZAX[®] reduced the total combined allergy symptoms and relief medication score during the birch pollen season – the primary endpoint – by 40% versus placebo. Furthermore, a similar clinical effect was demonstrated across the entire tree pollen season (hazel, alder and birch).

Birch trees are one of the most common causes of tree pollen allergy, and the condition is particularly prevalent in northern Europe, where it affects several million people. For some of these people, where their condition is not well controlled despite the use of symptom-relieving medications, ITULAZAX[®] may be a relevant treatment option. Germany is one of the largest AIT markets in the world and is a leader in the shift towards favouring evidence-based AIT. As a consequence, it is expected to become one of the most important markets for ITULAZAX[®].

The birch pollen season peaks in April in Germany, however, similarity between birch allergens and those of several other trees, known as birch-homologous species, means that symptoms can be triggered for an extended period of several months. Symptoms include itchy/watery eyes, blocked nose or itchy/runny nose, and sneezing. These can have a significant impact on quality of life, and many sufferers report issues with sleep, tiredness, mood-swings and even anxiety. As a result, they can lead to absences from work and school, impaired ability to work and, for students, can impact exam performance significantly.

ALK-Abelló A/S

For further information please contact:

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Media: Jeppe Ilkjær, mobile +45 3050 2014

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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