ACARIZAX® approved in Europe for treatment of young children

December 12, 2024

ALK (*ALKB:DC / OMX: ALK B*) today announced that its European regulatory filing for ACARIZAX® (house dust mite sublingual allergy immunotherapy tablet) in young children aged five to 11 has been approved by the health authorities in 21 EU countries via a type II variation procedure. The first market introductions, including in ALK's largest market, Germany, are expected to follow over the coming months.

The data that formed the basis for the approval includes results from the largest-ever paediatric AIT Phase 3 clinical trial, MT-12, which involved 1,458 children in North America and Europe. MT-12 was a randomised, placebo-controlled trial investigating the efficacy and safety of ACARIZAX® in children aged five to 11 with a clinical history of house dust mite-induced allergic rhinitis/conjunctivitis with or without asthma. The trial demonstrated efficacy and safety of the treatment in children, and the results were recently published in the reputable scientific journal, *The Lancet Regional Health – Europe*.

ALK's Executive Vice President of R&D, Henriette Mersebach (MD), says: " *Today, most children living with allergies are only treated with symptom-relieving medications, such as antihistamines or steroids. Despite this, many children still have uncontrolled symptoms and may benefit from effective treatment options that also address the underlying cause of their disease. Allergy induced by house dust mites often begins in early childhood and is associated with an elevated risk of developing into allergic asthma. Today's approval marks an important step forward for our ability to transform the medical treatment of children with allergies, as well as for ALK's long-term growth ambitions".*

Globally, it is estimated that more than ten million children, aged five to 11, have uncontrolled respiratory allergies and the number is growing. House dust mites are a common cause of allergy and closely linked to asthma.

The house dust mite tablet is marketed as ACARIZAX® in Europe and several international markets, as ODACTRA® in the USA, and as MITICURE™ in Japan. Until now, the tablet has been approved for use in young children only in Japan, where the vast majority of patients receiving treatment are children. In Europe, the tablet is now approved for use in patients aged five to 65 diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE blood test) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication. In addition, the tablet is approved for house dust mite-induced allergic asthma in patients aged 18-65.

A corresponding regulatory review is currently ongoing with the US Food and Drug Administration. Furthermore, a separate regulatory review of ALK's tree tablet ITULAZAX® is ongoing in Europe and Canada, also for use in children. These reviews are expected to complete in 2025.

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About ALK
ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy ('AIT') treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,900 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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