ALK’s European registration application for house dust mite SLIT-tablet in young children accepted for review

January 25, 2024

ALK (*ALKB:DC / OMX: ALK B / AKBLF*) today announced that the European regulatory filing for ACARIZAX® (house dust mite sublingual immunotherapy tablet) in young children has been accepted for review by the relevant health authorities via a type II variation. The European regulatory review process is anticipated to take up to nine months so that, subject to approval, the first market introductions in Europe could take place from late 2024/beginning of 2025.

The data used in the filing include results from a recently completed Phase 3 clinical trial involving 1,458 children in North America and Europe. The MT-12 trial was a randomised, placebo-controlled trial to study the efficacy and safety of ACARIZAX® in children aged five to 11 with a clinical history of house dust mite-induced allergic rhinitis with or without conjunctivitis (and with or without asthma). The trial was designed to demonstrate the effect of treatment of ACARIZAX® as measured by improvement in the total combined rhinitis score (TCRS) during the last eight weeks of the 12-month-treatment. The trial achieved its primary endpoint confirming an improvement of 22% compared to placebo.

ALK’s Executive Vice President of Research and Development, Henriette Mersebach, says: *“I’m pleased that our registration application for ACARIZAX® for young children has been accepted for review, and we are looking very much forward to the dialogue with the European authorities over the coming months. The results in children are robust and consistent with previous trial results and this filing represents an important step forward for our ability to transform the medical treatment of children with house dust mite allergy as well as for ALK’s long-term growth ambitions.”*

Globally, it is estimated that more than 10 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. Japan is currently the only country where the house dust mite tablet (MITICURE™) is approved for young children, while in other markets it is approved for the treatment of persistent moderate-to-severe house dust mite-induced allergic rhinitis for patients aged 12-65. In addition, in Europe, the tablet is also approved for house dust mite-induced allergic asthma in patients aged 18-65.

ALK expects to submit a corresponding application to the FDA in USA in the first half of 2024.

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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 2,800 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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