FDA approves ODACTRA® for the treatment of house dust mite allergy in young children

February 27, 2025

ALK (*ALKB:DC / OMX: ALK B*) today announced that the US Food and Drug Administration (FDA) has approved ALK's ODACTRA ® tablet for use in young children with house dust mite (HDM) allergy. ODACTRA® is now indicated to treat HDM-induced allergic rhinitis, with or without conjunctivitis, in children aged five through 11, in addition to patients aged 12 through 65.

ODACTRA® is an allergy immunotherapy (AIT) tablet which dissolves under the tongue and helps patients reduce their allergy symptoms and their reliance on symptomatic medication.

The FDA approval is an important step in ALK's efforts to make all its respiratory tablets available for all age groups – children, adolescents, and adults - in all relevant markets.

ALK's Executive Vice President of R&D, Henriette Mersebach (MD), says: " *I'm very pleased with the FDA approval of ODACTRA ® in young children, as this will enable us to provide an important and potentially life-changing treatment option for children who experience troublesome symptoms and impaired quality of life related to their allergic disease. Building upon our longstanding commitment to developing evidence-based innovative medicines, we now look forward to making ODACTRA® available for children through our US prescriber networks and through commercial and government markets*."

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 1,460 children in North America and Europe. 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.

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.

ALK's house dust mite allergy tablet is marketed as ODACTRA ® in USA, as ACARIZAX® in Europe and several international markets, as MITICURE™ in Japan, and as Sensimune™ in India. Until now, the tablet has been approved for use in young children in Europe and in Japan. A corresponding regulatory review is currently ongoing in Canada.

Furthermore, a separate regulatory review of ALK's tree tablet ITULAZAX ® also for use in children is currently ongoing in Europe and Canada. These reviews are expected to complete in 2025, after which all ALK's tablets will be approved for children, adolescents, and adults in relevant markets.

The approval is not expected to affect ALK's financial outlook for 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 2,800 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

- Company release_04_25UK_270225_ODACTRA_approval_children