



ACARIZAX® approved in Canada for treatment of young children

March 07, 2025

ALK (ALKB:DC / OMX: ALK B) today announced that Health Canada has approved ALK's ACARIZAX® tablet for use in children, aged five to 11, with house dust mite (HDM) allergy.

ACARIZAX® is now indicated for treatment of moderate to severe HDM-induced allergic rhinitis, with or without conjunctivitis, in children, adolescents, and adults in Canada aged five to 65.

Outside Europe, Canada is one of the most important markets for ALK's respiratory tablet portfolio with sales growing continuously by double digits. The expanded ACARIZAX® label is expected to further benefit market uptake in Canada.

Executive Vice President of R&D, Henriette Mersebach (MD), says: "*Children suffering from uncontrolled respiratory allergic rhinitis are impacted socially and in school, and they may face severe health implications. We look forward to providing this treatment option and helping more children in Canada live better lives.*"

The approval is based on the largest-ever paediatric AIT Phase 3 clinical trial, MT-12, involving 1,460 children aged five to 11 in North America and Europe. The trial demonstrated efficacy and safety of the treatment in children, and results were recently published in the scientific journal, *The Lancet Regional Health – Europe*.

The HDM-tablet has now been approved for use in young children and other age groups in Canada, Europe, the USA, and Japan, while regulatory reviews are ongoing in European countries outside the European Union as well as in rest of the world. The tablet is marketed as ACARIZAX® in Europe and international markets, as ODACTRA® in the USA, as MITICURE™ in Japan, and as Sensimune™ in India.

In parallel, separate regulatory reviews of ALK's tree pollen allergy tablet ITULAZAX® are ongoing in Europe and Canada, for use in young children and adolescents. These reviews are expected to complete in the middle of 2025, after which ALK will have four tablets, covering 80% of the most prevalent respiratory allergies, approved for children, adolescents, and adults in Europe and Canada. Approximately 10 million children suffer from uncontrolled respiratory allergy.

This announcement does not impact ALK's financial guidance for 2025.

ALK-Abelló A/S

For further information please contact:

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

Media: Maiken Riise Andersen, tel. +45 5054 1434

About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. ALK manufactures and 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

- [InvestorNews_07Mar25_Acarizax children approval in Canada](#)