Large Phase 3 clinical trial successfully meets primary endpoint, confirming the potential of ALK's house dust mite tablet in young children

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- **Primary and all key secondary confirmatory endpoints were met, with an improvement in the total combined allergic rhinitis score (TCRS) of 22% compared to placebo (primary endpoint). Results were highly statistically significant and consistent across multiple endpoints**
- **The Phase 3 efficacy and safety trial of ALK's house dust mite tablet involved 1,458 children aged 5 to 11 in North America and Europe**
- **One of the largest ever paediatric allergy immunotherapy trials and a key element of ALK's strategy of expanding its tablet portfolio to cover all relevant age groups**

ALK (ALKB:DC / OMX: ALK B / AKBLF) today announced top-line results from a Phase 3 paediatric clinical trial of its sublingual allergy immunotherapy tablet for the treatment of house dust mite (HDM)-induced allergic rhinitis. The HDM tablet is marketed as ACARIZAX® in Europe and a number of international markets, as ODACTRA® in the USA, and as MITICURE™ in Japan.

The trial achieved its primary endpoint with an improvement of 22% in the total combined rhinitis score (TCRS) compared to placebo treated patients. Results were highly statistically significant ($p<0.0001$), with a lower bound of the 95%-confidence interval of 12%, versus a threshold criterion of minimum 10% as required by the US Food and Drug Administration (FDA). The trial also demonstrated that the treatment was well tolerated and had a favourable safety profile, similar to the safety profile reported in adolescents and adults. All key secondary endpoints were also met, further confirming the efficacy of the HDM tablet. The trial was well conducted with more than 95% of patients maintaining treatment throughout the trial. This trial confirms earlier results reported in ALK's adult HDM tablet trials and was conducted in accordance with ALK's strategy to focus on children and to treat allergies at an early stage in life.

The trial, which involved 1,458 children in North America and Europe, was a Phase 3, randomised, placebo-controlled trial to study the efficacy and safety of ALK's HDM tablet in children aged 5 to 11 with a clinical history of HDM-induced allergic rhinitis with or without conjunctivitis (and with or without asthma). The trial was designed to demonstrate the effect of treatment with the HDM tablet as measured by improvement in allergy symptoms and reduction in allergy pharmacotherapy use during the last eight weeks of the 12-month-treatment.

ALK's Executive Vice President of Research and Development, Henriette Mersebach, says " *The successful and unprecedented outcome of the trial will allow us to make a valuable difference for the many children living with house dust mite allergy. The results are very robust and consistent with previous trial results, and clearly confirm the benefits of treating childhood allergies with our tablets. The outcome is also important for ALK's long-term growth ambitions and our ability to transform the medical treatment of children with allergies. We have already seen the real-world importance of paediatric indications for our tablets, especially in Japan, where children constitute the majority of new patients.*"

Globally, it is estimated that more than 10 million children, aged 5 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 HDM tablet (MITICURE™) is approved for young children, while in other markets it is approved for the treatment of persistent moderate-to-severe HDM-induced allergic rhinitis for patients aged 12-65. In addition, in Europe, the tablet is also approved for HDM-induced allergic asthma in patients aged 18-65.

ALK will now pursue a dialogue with relevant regulatory authorities about expanding the current product indications. Subject to approval, the HDM tablet could be available for young children in Europe and North America in 2024/25. ALK expects to present the further details from the trial at a scientific congress later in 2023/24. In line with ALK's commitment to secure approvals for all of ALK's respiratory tablets covering paediatric, adolescent, and adult use, ALK is also completing a pivotal, Phase 3 paediatric trial with its tree pollen tablet (ITULAZAX®). ALK expects to report top-line results from this trial in Q4 2023.

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This information is information that ALK is obliged to make public pursuant to the EU Market Abuse Regulation.

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 2,700 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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