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

- **The Phase 3 efficacy and safety trial of ALK's tree tablet involved 952 children aged 5 to 17 in Canada and Europe.**
- **ALK has now successfully completed pivotal clinical development for all five respiratory allergy immunotherapy tablets across 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 tree-pollen-induced allergic rhinoconjunctivitis. The tree tablet is marketed as ITULAZAX® in Europe and as ITULATEK® in Canada for patients aged 18 to 65.

The trial achieved its primary endpoint and confirmed the effect of the tree tablet with an improvement of 22% in the total combined rhinoconjunctivitis score (TCS) during the birch pollen season compared to placebo. Results were highly statistically significant (p=0.0004), with a lower bound of the 95%-confidence interval of 10.6%. The trial also demonstrated improvement in TCS during the entire tree pollen season (key secondary endpoint). In addition, the trial demonstrated that treatment with the tree tablet was well tolerated and had a favourable safety profile, similar to the safety profile reported in other trials. The trial was well conducted with 96% of patients completing the trial. This trial confirms previous results reported in ALK's 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 952 children in Canada and Europe, was a Phase 3, randomised, placebo-controlled trial to study the efficacy and safety of ALK's tree tablet in children aged 5 to 17 with a clinical history of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from birch trees as well as from other trees belonging to the birch homologous group. The trial was designed to confirm the effect of treatment with the tree tablet as measured by improvement in allergy symptoms and reduction in allergy pharmacotherapy use during the 2022 and 2023 pollen seasons.

ALK's Executive Vice President of Research and Development, Henriette Mersebach, says: *"With the outcome of this large clinical trial, we have now successfully completed our paediatric development of all of ALK's sublingual AIT tablets in respiratory allergies. The study results are consistent with previous tablet trial results and clearly confirms the benefits of treating respiratory allergies with our AIT tablets already from early childhood. This positive outcome is also important for ALK's long-term growth ambitions and our ability to transform the medical treatment of children with allergies."*

Globally, it is estimated that more than 10 million children have uncontrolled respiratory allergies, and the number is growing. Tree pollen is a common cause of these uncontrolled allergies.

ALK will now pursue a dialogue with relevant regulatory authorities about expanding the current product indications. Subject to approval, the tree tablet could become available for young patients in Europe and Canada in 2025. ALK expects to present further details from the trial at a scientific congress in 2024. In line with ALK's commitment to secure approvals for all of ALK's respiratory tablets covering paediatric, adolescent, and adult use, ALK has also recently successfully completed a pivotal, Phase 3 paediatric trial with its house dust mite tablet (ACARIZAX®).

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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.