

ALK presents positive phase 3 paediatric trial data offering new hope for children with respiratory allergies

At the Annual Congress of the European Academy of Allergy and Clinical Immunology (EAACI) which took part in Valencia in Spain from 31 May to 3 June 2024, the Danish pharmaceutical company ALK presented new data from two paediatric phase 3 clinical trials evaluating SQ sublingual immunotherapy (SLIT) tablets in house dust mite (HDM) and tree pollen respiratory allergy.

ALK contributed with a total of 18 scientific abstracts within the EAACI 2024 scientific programme – this included groundbreaking findings from two pivotal paediatric phase 3 clinical trials:

- MT-12: A placebo-controlled phase 3 trial evaluating the efficacy and safety of the SQ HDM SLIT-tablet in children (5-11 years of age) with HDM allergic rhinitis/rhinoconjunctivitis with or without asthma.
- TT-06: A placebo-controlled phase 3 trial evaluating the efficacy and safety of the SQ tree SLIT-tablet in children and adolescents (5-17 years of age) with moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from birch and trees belonging to the birch homologous group.

The paediatric phase 3 data were presented in four oral abstract presentations during the EAACI Annual Congress by key trial investigators unveiling promising results in treating children by confirming the efficacy and safety of SLIT-tablets in paediatric populations with respiratory allergy caused by HDM or tree pollen (birch homologous group).

As part of the EAACI programme, the new phase 3 data were also presented at the ALK symposium which took place on Saturday 1 June, emphasising the clinical importance of these new data.

New clinical evidence for SLIT-tablets documenting positive impact on children's daily lives

The scientific presentations of the new paediatric phase 3 data demonstrated new clinical evidence documenting the efficacy and safety of the HDM and tree SLIT-tablets in children, by showing reductions in clinical symptoms and medication use, and improved quality of life in the younger children suffering from respiratory allergies.

The SLIT-tablets were generally well-tolerated with a favourable safety profile, similar to the safety profile reported in previous trials. This emphasises the importance of treating allergies in children at an early stage in life and the clinical relevance of developing future treatment strategies for this important age group.

Henriette Mersebach, Executive Vice President of Research & Development at ALK says:

“The global impact of respiratory allergies in the younger population underscores our responsibility to address and alleviate the burden of this condition, highlighting the value of generating new paediatric phase 3 data for the SQ SLIT-tablet portfolio of therapeutic solutions. This is an important step towards helping many more children live better lives without the burden of allergy.”

Tablet indications expected in 2024/2025

ALK's presence at the EAACI 2024 Congress has emphasised its commitment to advancing allergy treatment and improving the lives of people affected by respiratory allergic disease.

ALK has submitted a regulatory filing of the HDM SLIT-tablet in younger children (5-11 years) for review by relevant health authorities. Subject to approval, the first market introductions in Europe could take place from late 2024/beginning of 2025. ALK has also recently submitted a regulatory filing of the tree SLIT-tablet to apply for an expansion of the current indication to include children 5-17 years of age. Subject to approval, the tree tablet could become available for young patients in Europe and Canada in 2025.

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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 2,900 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net