ALK’s pivotal phase 3 trial in children published in reputable scientific journal

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The reputable scientific journal, *The Lancet Regional Health – Europe*, has published robust results from ALK’s house dust mite sublingual allergy immunotherapy tablet (SLIT-tablet) phase 3 children trial, MT-12, evaluating the efficacy and safety in children (5-11 years) with house dust mite allergic rhinitis.[1]

With the acceptance for publication, ALK’s MT-12 phase 3 trial has been evaluated by the journal for its methodology, relevance, and clinical implications. This scrutiny helps ensure that only high-quality research is disseminated and underlines that ALK is among top researchers within its field.

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

“Having our successful MT-12 phase 3 trial published in this highly esteemed journal demonstrates that the research has undergone rigorous peer review and meets high scientific standards, and it is a significant mark of recognition within the scientific community.”

This trial confirms earlier results reported in ALK’s adult house dust mite tablet trials and was conducted in accordance with ALK’s clinical development strategy to focus on children and to target allergies at an early stage in life.

Important to expand evidence

This pivotal phase 3 trial is an important advancement in expanding the evidence of allergy immunotherapy in children and represents the largest paediatric, randomised controlled trial conducted to date with house dust mite allergy immunotherapy.

Henriette Mersebach says:

“The global impact of respiratory allergies in the younger population underscores our responsibility to address and alleviate the burden of this disease. The MT-12 publication in The Lancet Regional Health – Europe highlights important new paediatric phase 3 data for the house dust mite SLIT-tablet and is essential for expanding the evidence of allergy immunotherapy to help more children live better lives by reducing the burden of allergy in the future.”

Earlier this month, the results from another phase 3 children trial from ALK, the TT-06 tree SLIT-tablet clinical trial, was published in the scientific journal, Allergy, evaluating the efficacy and safety in children (5-17 years) with tree pollen induced allergic rhinoconjunctivitis[2]. This publication further adds to the credibility and validation of ALK’s successful trial results.

With these two trials, ALK and Japanese partner, Torii have completed a total of 14 phase 3 children trials with the SLIT-tablets enrolling paediatric populations with respiratory allergy induced by grass, ragweed, tree and Japanese cedar pollen, and house dust mites.

Advancements in allergy treatment in young children across key markets

The house dust mite SLIT-tablet is marketed as ACARIZAX® in Europe and a number of international markets, as ODACTRA® in the USA, and as MITICURE™ in Japan. Japan is currently the only country where the house dust mite SLIT-tablet (MITICURE™) is approved for young children, while in other markets it is approved for the treatment of persistent moderate-to-severe house dust mite-induced allergic rhinitis for patients aged 12-65. In addition, in Europe, the tablet is also approved for house dust mite-induced allergic asthma in patients aged 18-65.

The tree SLIT-tablet is marketed as ITULAZAX® in Europe and as ITULATEK® in Canada for patients aged 18 to 65 with moderate-to-severe allergic rhinitis and/or conjunctivitis induced by tree pollen[3].

The regulatory processes to secure approvals of the house dust mite and tree SLIT-tablets for children are ongoing, but subject to approval, the indications could become available in 2024/2025 in Europe and North America.

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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.

About the MT-12 and TT-06 trial designs

MT-12 trial design
The randomised, double-blind, placebo-controlled trial took place between October 2019 and April 2023 and enrolled 1460 children (5-11 years) with moderate to severe house dust mite allergic rhinitis or rhinoconjunctivitis. Children were treated daily with either the house dust mite SLIT-tablet or placebo for one year. The trial was conducted at 95 sites in Europe and North America.

The primary objective was to demonstrate efficacy of the house dust sublingual tablet compared to

placebo based on the total combined rhinitis symptom and medication use during the primary efficacy assessment period.

The main secondary objectives were to demonstrate efficacy of the house dust mite sublingual tablet compared to placebo based on rhinitis symptoms, rhinitis medication use, combined rhinoconjunctivitis symptoms and medication use, quality of life, and to evaluate safety and tolerability.

TT-06 trial design
The randomised, double-blind, placebo-controlled trial took place between April 2021 and July 2023 and enrolled 952 children (5-17 years) with moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from birch and trees in the birch homologous group. Children were treated daily with either the tree SLIT-tablet or placebo pre-seasonally and throughout one tree pollen season. The trial was conducted at 80 sites in Europe and Canada.

The primary objective was to demonstrate efficacy of the tree sublingual tablet compared to placebo based on total combined rhinoconjunctivitis symptom and medication use during the birch pollen season.

The main secondary objectives were to demonstrate efficacy of the tree sublingual tablet compared to placebo based on the combined rhinoconjunctivitis symptom and medication use during the tree pollen season, rhinoconjunctivits symptoms, medication use and quality of life during both the birch and tree pollen season, and to evaluate safety and tolerability.

About the journal: The Lancet Regional Health – Europe
The Lancet Regional Health – Europe is an open access journal, part of The Lancet's global initiative to advocate for health-care quality and access in all regions of the world. The journal fosters the advance of clinical practice and health policy in the European region, with the ultimate goal of improving health outcomes. It aspires to increase the quality of regional and national health research.
The journal publishes high-quality original research that advocates change in, or illuminates, clinical practice and health policy in the European region. It also considers relevant reviews, commentaries, and opinion pieces. The journal invites submissions that are pertaining to regional health topics, including but not limited to prevention and management of infections and non-communicable diseases, improvement of healthy ageing, mental health, and the reduction of health inequalities.
The journal can be found at www.thelancet.com/journals/lanepe/home

About the journal: Allergy
Allergy, the official journal of the European Academy of Allergy and Clinical Immunology (EAACI), aims to advance, impact and communicate all aspects of the discipline of Allergy/Immunology, including educational, basic, translational and clinical research, and to maintain contact between basic and clinical Allergy/Immunology. Allergy is an international peer-reviewed journal with contributors and readers from all countries. The journal publishes original articles, reviews, position papers, guidelines, editorials, news and commentaries, letters to the editors and correspondences.
The journal can be found at https://onlinelibrary.wiley.com/journal/13989995

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[1] The results were published online on 26 November 2024: Schuster et al. The Lancet Regional Health – Europe 2025;48: 101136. https://doi.org/10.1016/j.lanepe.2024.101136

[2] The results were published in the scientific journal, *Allergy*, on November 4: Gappa M, et al. Allergy. 2024;00:1-12. doi: 10.1111/all.16363.

[3] Members of the birch homologous group

Attachment

- Press release_phase 3 trial published in reputable journal_final