



ALK completes first part of phase 1 trial with peanut SLIT-tablet

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- The trial now progresses into its second part, expected to complete later in 2024.
- ALK to submit a protocol amendment for Phase 1-2 efficacy trial extension.

ALK (ALKB:DC / OMX: ALK B / AKBLF) announced today that it has completed the first part of its phase 1 clinical trial (named 'ALLIANCE') for its investigational sublingual immunotherapy ('SLIT') tablet for the treatment of peanut allergy.

The first part of the trial investigated the safety and tolerability of 14 days treatment with the peanut tablet at different starting doses. For all dose levels, the peanut tablet was shown to be safe and tolerable and with a safety and tolerability profile in accordance with that of the approved SLIT-tablets (ACARIZAX/ODACTRA®, GRAZAX®/GRASTEK®, RAGWIZAX®/RAGWITEK®, ITULAZAX®/ITULATEK®). No serious adverse events and no cases of treatment emergent anaphylaxis were reported. Based on results from part 1, the starting dose for the second part of the study has been selected. This part of the study will evaluate the safety and tolerability of up-dosing to the highest tolerable maintenance dose. The second part will be initiated imminently and is scheduled to complete later in 2024.

Furthermore, ALK has decided to amend the ALLIANCE study protocol to include a third part involving approximately 100 additional patients. This part will evaluate safety and efficacy of the peanut SLIT-tablet as assessed by an oral food challenge following a period of maintenance treatment. The implementation of the third part is contingent upon a successful outcome of the second part. The revised protocol is expected soon to be submitted to the relevant authorities.

ALK's Executive Vice President of Research and Development, Henriette Mersebach, says: " We are pleased to report positive progress in our ALLIANCE trial, addressing potentially life-threatening peanut allergy. Encouraged by the initial results for the peanut tablet, we have made a provisional decision to extend the trial into a seamless Phase 1-2 design allowing us to explore the efficacy of the tablet as well. Leveraging our profound R&D expertise, we remain committed to developing valuable new treatment options for people with allergy".

In the USA, peanut allergy affects up to 1.5 million children and adolescents aged 4-17, while in Europe, around 1 million children and adolescents are affected by this potentially life-threatening condition. The disease often presents in early childhood and can last a lifetime. For some of these patients, allergy immunotherapy may become a relevant treatment option with the potential to improve quality of life, both for them and their families.

This announcement is not expected to materially change the R&D cost outlook for 2024-25.

ALK-Abelló A/S

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

About the ALLIANCE trial

Initiated in 2022, the ALLIANCE trial was designed to assess the tolerability and safety of an up-dosing regimen with a once-daily peanut SLIT-tablet in adults, adolescents, and children. The trial is a phase I, open-label, dose-escalation, multi-site trial conducted in North America, with approximately 100 participants with peanut allergy confirmed by screening via a double-blind, placebo-controlled food challenge. The first part of the trial aimed at determining the starting dose of the up-dosing regimen and the second part to assess safety and tolerability of the up-dosing regimen as well as gather early data on its biological action. The third part intends to investigate safety and efficacy of selected doses of the peanut SLIT-tablet compared with placebo. The trial marked the formal start of ALK's clinical development of a novel food allergy treatment which uses the same technology as ALK's SLIT tablets for respiratory allergies.

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 2,800 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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