
Positive results advance peanut tablet to phase II development

- **ALK's peanut tablet shown to be safe and tolerable across multiple doses.**
- **Development now advances to phase II for dose finding and efficacy.**
- **First patients in phase II to receive first doses imminently. Trial expected to complete in 2026.**

ALK (ALKB:DC / OMX: ALK B) today announced positive interim results from its phase I/II clinical trial (named 'ALLIANCE') for its investigational sublingual immunotherapy ('SLIT') tablet for the treatment of peanut allergy.

This part of the trial, which involved approximately 30 patients, investigated safety and tolerability of multiple doses of the peanut tablet across the up-dosing regimen. Each patient received daily dosing for ten weeks. For all dose levels, the tablet was shown to be safe and tolerable. The vast majority of treatment-emergent side effects were transient, mild to moderate, local application site reactions. No serious adverse events and no cases of treatment emergent anaphylaxis were reported.

ALK's Executive Vice President of R&D, Henriette Mersebach, says: "We are very excited to report further positive progress with our ALLIANCE trial, which addresses the potentially life-threatening peanut allergy. We are beginning to see the contours of a simple, convenient, and safe medicine that may become an important treatment option for patients whose life is profoundly impacted by the disease."

Based on the results, treatment doses for phase II have been selected. This part will evaluate safety and efficacy of two different dosing regimens against placebo as assessed by an oral food challenge after a period of maintenance treatment. The selected doses are furthermore in the range of external data demonstrating clinically meaningful efficacy. The phase II part is expected to involve approximately 125 patients (aged four to 65) in the USA and Canada and is scheduled to complete in 2026. The first patients will receive first doses imminently.

Provided a successful phase II outcome, ALK intends to advance the peanut SLIT-tablet into phase III development after which it can be submitted for regulatory approval, expectedly towards the late 2020s.

In the USA, peanut allergy affects up to 1.5 million children and adolescents aged four to 17, while in Europe, approximately one 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 themselves and their families.

The peanut tablet spearheads ALK's future portfolio in food allergy, which also spans novel concepts in pre-clinical development targeting other pathways and indications.

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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/II, dose-escalation, multi-site trial conducted in North America, with approximately 200 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 aimed at assessing safety and tolerability of the up-dosing regimen as well as gathering early data on its biological action. The third part will investigate safety and efficacy of selected doses of the peanut SLIT tablet compared with placebo. The ALLIANCE 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.