ALK announces successful outcome of phase 2 trial with its tablet for treatment of peanut allergy demonstrating early onset of efficacy

Inside Information

- **The ALLIANCE phase 2 trial demonstrated proof-of-concept after only 6 months of maintenance treatment in a broad patient population comprising both children and adults.**
- **Clear dose-dependent and statistically significant efficacy was demonstrated across multiple efficacy endpoints based either on the Tolerated Dose[1] ('TD') or Eliciting Dose[2] ('ED') as measured by a double-blind, placebo-controlled food challenge with peanut protein.**
- **Efficacy was observed across all age groups.**
- **Treatment with the peanut tablet was safe and well-tolerated. Treatment-related discontinuations were low. No reports of treatment-related anaphylaxis or treatment-related serious adverse events.**
- **Development to progress rapidly into phase 3, expected to be initiated late 2026 pending regulatory feedback on the final trial design.**

ALK (ALKB:DC / Nasdaq Copenhagen: ALK B) today announced positive topline results from the phase 2 clinical trial (named 'ALLIANCE') with its once-daily investigational sublingual immunotherapy ('SLIT') tablet for the treatment of peanut allergy in patients aged 4-65 years.

The trial included 150 patients and was a randomised, double-blinded placebo-controlled dose-finding phase 2 clinical trial evaluating safety and efficacy of two different doses of the peanut tablet compared to placebo. Patients were up-dosed followed by maintenance dosing for 24 weeks.

After only 24 weeks of maintenance treatment, clear dose-dependent and statistically significant efficacy was demonstrated across multiple efficacy endpoints based either on the Tolerated Dose (TD) or Eliciting Dose (ED) as measured by a double-blind, placebo-controlled exit food challenge with peanut protein:

- **TD300 efficacy endpoint**: **49%** of patients treated with the highest dose of the peanut tablet tolerated a dose of 300 mg peanut protein vs. 18% in placebo ($p<0.001$).
- **TD600 efficacy endpoint: 31%** of patients treated with the highest dose of the peanut tablet tolerated a dose of 600 mg peanut protein vs. 8% of the placebo treated patients ($p<0.01$).
- **TD1000 efficacy endpoint**: **22%** of patients treated with the highest dose of the peanut tablet tolerated a dose of 1.000 mg peanut protein vs. 2% in placebo ($p<0.01$).
- **ED based efficacy endpoint[3]: 65%** of patients treated with the highest dose of the tablet responded to treatment when defining responders as patients with a baseline ED ≤ 30 mg who achieved an ED ≥ 300 mg or a patient with a baseline of ED = 100 mg who achieved an ED ≥ 600 mg of peanut protein during the oral food challenge (24% in placebo, $p<0.001$).

Efficacy was observed across all age groups. Treatment with the tablet was safe and well-tolerated across all treatment groups, and the level of treatment-related discontinuations was low. No treatment-related anaphylaxis or treatment-related serious adverse events were reported.

ALK's President and CEO Peter Halling, says: "*We are excited to report a successful outcome of the ALLIANCE trial, which addresses the potentially life-threatening peanut allergy. This is the first time ever that we see a strong proof of concept with our tablet technology in food allergy. We are beginning to see the contours of an effective, safe, and convenient medicine that may become an important treatment option for patients whose life is profoundly impacted by the disease*."

He continues: "*Based on these very encouraging phase 2 results, we will now optimise our plans for phase 3 development of the peanut tablet, which is expected to be initiated towards the end of 2026, pending dialogue with the healthcare authorities on the final trial design.*"

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.

ALK-Abelló A/S

For further information please contact:

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Media: Maiken Riise Andersen, tel. +45 5054 1434

This announcement contains inside information. This is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

About peanut allergy

Peanut allergy is an IgE-mediated food allergy in which ingestion of peanut proteins triggers immediate hypersensitivity symptoms and can cause anaphylaxis; it typically begins in early childhood and often persists into later life. It is often a severe and potentially life-threatening condition, which accounts for one of the highest rates of anaphylaxis within food allergies. More than 10 million people in Europe, the USA, and Canada have peanut allergy, more than 3 million of these are children and adolescents. Currently, there are only limited treatment options available, and for some of these patients, sublingual allergy immunotherapy tablets may become a relevant treatment option with the potential to improve quality of life, both for themselves and their families.

About the ALLIANCE trial

Initiated in 2022, the ALLIANCE trial was designed to assess the tolerability, safety and efficacy of an up-dosing regimen with a once-daily peanut SLIT tablet in adults, adolescents, and children. The trial was a phase I-II, multi-site trial conducted in North America, with 216 enrolled 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 (phase II) investigated 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. ALK's activities cover the entire value chain of developing, sourcing, producing, and marketing a diversified portfolio of products for diagnosing and treating respiratory allergies and severe allergic reactions (anaphylaxis) in both children and adults. Headquartered in Denmark, ALK employs around 2,700 people worldwide and is listed on Nasdaq Copenhagen (Nasdaq: ALK B). Visit us at www.alk.net.

[1] Tolerated dose: The highest dose administered during a standardised oral food challenge that elicits either no symptoms or symptoms that are not clearly indicative of an allergic reaction.
[2] Eliciting dose: The lowest dose administered during the oral food challenge that induces the onset of unequivocal allergy symptoms (the dose that stops the food challenge and that is not tolerated).
[3] Result based on pre-specified analysis. The ED-based efficacy endpoint saw a responder rate of 69% (25% in placebo, p<0.001) if using a post-hoc analysis with multiple imputation of missing data.