ALK begins clinical trial of its SLIT-tablet for the treatment of peanut allergy

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ALK (*ALKB:DC / OMX: ALK B / AKABY / AKBLF*):

- **ALK initiates a Phase I clinical trial of its novel investigational sublingual allergy immunotherapy (SLIT) tablet for the treatment of peanut allergy.**
- **The trial marks the formal start of clinical development of the peanut SLIT-tablet which uses same technology as ALK's SLIT-tablets for respiratory allergies.**

ALK announced today that it is initiating Phase I clinical development of its investigational SLIT-tablet for the treatment of peanut allergy. Under the name Alliance, the trial will be conducted in North America and will assess the tolerability and safety of an up-dosing regimen with a once-daily peanut SLIT-tablet.

ALK first announced its intention to establish a presence in the treatment of food allergies in early 2021. Initiation of the Alliance Phase I trial follows the successful completion of a feasibility study in late-2021, which confirmed that the same technology used in ALK's SLIT-tablets for respiratory allergies, was also suitable for use in the peanut SLIT-tablet.

In all, approximately 100 adults, adolescents and children, who have a confirmed peanut allergy, will participate in the trial, which is expected to involve up to 15 centres. Screening of patients will begin soon and, and the trial is scheduled to complete in 2023.

Henrik Jacobi, ALK's Executive Vice President of R&D, said: *"Peanut allergy is an area of significant unmet medical need, and ALK is committed to seeking new solutions that address the needs of people who live with this potentially life-threatening condition. We will use our profound R&D expertise, and the extensive experience gained in the clinical development of our SLIT-tablets for respiratory allergies, to develop a potentially valuable new treatment option for prescribers and their peanut-allergic patients."*

The Alliance trial is a Phase I, open-label, dose-escalation, multi-centre trial, with participants screened via double-blind, placebo-controlled food challenges to confirm their peanut allergy. There will be two stages to the trial. The first is designed to determine the starting dose of the up-dosing regimen, and the second to assess the tolerability of the up-dosing regimen. Further objectives are to assess the safety of the peanut SLIT-tablet and, in the second stage, to gather early data on its biological action. The trial will consist of up to 10 cohorts, split evenly between the two stages of the trial.

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.

Alongside its work to develop a peanut SLIT-tablet, ALK is also further developing its range of respiratory SLIT-tablets in order to extend their coverage to children and adolescents in more markets, and is currently conducting Phase III paediatric trials of its house dust mite and tree pollen SLIT-tablets.

ALK-Abelló A/S

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

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 2,600 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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