New clinical trial for ALK's house dust mite tablet paves the way for early registration in China

- **Small-scale Phase III trial replaces larger trial in agreement with China's regulators and reduces development costs and time to market by several years**
- **First Chinese patients have been recruited and randomised following exposure to house dust mite (HDM) allergens in a controlled environment**
- **China is potentially the world's largest market for HDM allergy, with more than 75 million people affected and just 300,000 receiving AIT**
- **ALK's HDM SLIT-tablet would represent a major innovation on the market and could launch as early as 2023**

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) has initiated a new Phase III clinical trial which is expected to significantly reduce development costs and time to market in China for its sublingual allergy immunotherapy (SLIT) tablet against house dust mite (HDM) allergy.

Subject to satisfactory results and a subsequent regulatory approval, it could allow ALK to target a product launch in China as early as 2023, thereby gaining access for its HDM tablet to a sizeable new market with significant unmet medical need. ALK currently serves the market with its own organisation with a range of diagnostic and SCIT products (also known as allergy shots).

Professor Luo Zhang, the trial's leading principal investigator in China said: *"China has the potential to become the world's largest house dust mite allergy market, with more than 75 million HDM allergic people against a backdrop of 300,000 who currently receive AIT treatment. The existing market is served by a number of local suppliers, however, none of them offer a SLIT-tablet such as ALK's, which would represent a major innovation on the market."*

The new trial involves approximately 200 patients and replaces a planned larger-scale Phase III field trial in allergic rhinitis patients in China. Trial participants are currently being recruited in China and will receive treatment there over a 24-week period. Prior to, and after, the 24 weeks of treatment, trial participants will travel to Vienna, Austria, where they will be exposed to house dust mite allergens in a controlled environment so that an assessment of treatment effect can take place. This will be done by comparing the pre-treatment baseline and post-treatment responses to their allergic symptoms.

The replacement of the large-scale Phase III trial with this shorter trial – known as an 'environmental exposure chamber trial' due to the specially designed room, or chamber, where participants are exposed to the house-dust mite allergens – is expected to reduce the time to market for the HDM tablet in China by several years.

ALK's Executive Vice President of Research and Development, Henrik Jacobi, said:
"This innovative solution to a requirement from China's regulators is a testament to the creative efforts of our dedicated and highly professional clinical and regulatory affairs team, as well as the engagement and flexibility of the responsible authorities in China. Our substantial experience with the tablet portfolio, including 16 clinical house dust mite trials involving more than 4,000 patients, gives both parties every confidence that this new trial will provide sufficient additional data for a regulatory filing much sooner than originally planned."

The new trial is a randomised, parallel-group, double-blind, placebo-controlled Phase III trial involving approximately 200 subjects with HDM-induced allergic rhinitis. Subjects will be randomised into two groups of equal size, one of which will receive treatment with ALK's HDM tablet, while the other receives placebo.

ALK's HDM tablet was first launched in 2015 and is currently available in Europe, the USA and Canada, Japan, as well as several International markets where it is sold under the brand names ODACTRA® (USA), MITICURE™ (Japan), and ACARIZAX® (elsewhere). It is currently sold in a total of 19 countries with indications covering both allergic rhinitis and allergic asthma, and for use in children, adolescents and adults. The specific details of each approval vary according to country. Following the analysis and reporting of results from the new trial, ALK expects to file for regulatory approval of the HDM tablet in China soon afterwards.

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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 2,400 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net