

Phase 3 trial in China successfully confirms ACARIZAX[®] safety and efficacy in patients with house dust mite allergy

Inside Information

- **Phase 3 trial with ACARIZAX[®] in Chinese participants met the primary objective and showed efficacy in line with previous trials, after only 24-28 weeks of treatment.**
- **ACARIZAX[®] was shown to be safe and well-tolerated, consistent with data obtained in previous trials over the past 10+ years.**
- **ALK will now work with its partner GenSci to file for regulatory approval of ACARIZAX[®] in China. Filing is expected in first half of 2027.**

ALK (ALKB:DC / Nasdaq Copenhagen: ALK B) today announced positive topline results from the phase 3 bridging trial evaluating the efficacy and safety of its house dust mite ('HDM') sublingual immunotherapy ('SLIT') tablet, ACARIZAX[®], in Chinese participants aged 12 - 65 years with HDM allergic rhinitis/rhinoconjunctivitis, with or without asthma. The trial was designed to show a consistent trend with the previous clinical trials conducted with ACARIZAX[®] outside China.

Participants were treated for 24-28 weeks with either ACARIZAX[®] or placebo. The primary endpoint was the average daily total combined rhinitis score ('TCRS') during the primary efficacy assessment period. The TCRS was measured by recording the allergy symptoms and pharmacotherapy use in the last 4 weeks of treatment.

The trial achieved its primary objective. The absolute treatment difference of the TCRS was 1.11 (with a lower bound of the 95% confidence interval exceeding zero; the relative difference was 19.1%) favouring ACARIZAX[®] over placebo, thereby substantially exceeding the predefined success criterion that was agreed with the Chinese authorities. The trial also demonstrated the treatment to be safe and well-tolerated in both the adolescent and adult age groups in line with the safety profile established with previous trial results.

The trial performed well across endpoints as well as key measures of trial conduct, including participant retention and treatment compliance:

- A favourable treatment difference was observed in the overall population, and in both adult and adolescent subgroups
- Early onset of efficacy was demonstrated from week 8, during the first TCRS efficacy assessment period
- When asked to compare their rhinitis symptoms before and after treatment, participants treated with ACARIZAX[®] were 4.3 times more likely to feel better at the end of the trial than those who received placebo
- The trial was executed successfully, with high treatment compliance and low participant dropout rates.

Jacob Glenting, EVP and Head of Global R&D, says: *"The results of our phase 3 clinical trial in China are robust and highly consistent with more than a decade of data on our house dust mite tablet, confirming that it is both efficacious and safe for Chinese patients and can make a real difference for allergy sufferers in China. Together with our partner GenSci, we will now continue the dialogue with the Chinese health authorities to seek regulatory approval, so that we can make this treatment available to the millions of people in China living with house dust mite allergy."*

The trial was a randomised, double-blind, placebo-controlled, multi-site phase 3 registration trial conducted in China, enrolling 327 participants who received a once-daily treatment with ACARIZAX[®]

or placebo for 24-28 weeks. The trial was designed to generate Chinese clinical data which, together with existing global data, is expected to support local regulatory approval of ACARIZAX®.

Subject to approval by the Chinese authorities, ACARIZAX® will be added to GenSci's portfolio under the partnership agreement announced in September 2025 (company release No 15/2025).

Worldwide, China is the country with the highest number of people suffering from house dust mite allergy. Yet the market remains significantly underpenetrated with estimated more than 100 million affected and less than 1 million people currently receiving allergy immunotherapy treatment.

The trial results do not affect ALK's financial guidance for 2026.

ALK-Abelló A/S

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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 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 2,800 people worldwide and is listed on Nasdaq Copenhagen (Nasdaq: ALK B). Visit us at www.alk.net.

About Changchun GeneScience Pharmaceutical Co., Ltd. ("GenSci")

GenSci is a leading biopharmaceutical company in China, specialising in paediatric and women's health. Additionally, GenSci is active in other therapeutic areas: Endocrinology, Metabolic, Immunology/Respiratory, and Oncology. The company has over 8,000 employees, and integrates research, development, production, and marketing of innovative therapies in its value chain. Established in 1997, the company is a subsidiary of Changchun High-Tech Industries (Group) and is headquartered in Changchun, China. Find more information at www.genscigroup.com/en.