Clinical trial waiver in China opens door to 2022 registration filing for ALK's dust mite allergy tablet

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

- **A waiver from Chinese authorities allows ALK to file for regulatory approval in China without finalising its paused local registration trial**
- **China is potentially the world's largest market for house dust mite allergy treatment, with more than 75 million people affected, and just 300,000 on allergy immunotherapy**

ALK today announced that it expects to submit a registration application in China for its house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet already in 2022.

In preparation for this application, ALK has completed a Phase I trial in China and had initiated a Phase III, local registration trial in adult allergic rhinitis. However, the Phase III trial has been paused since 2020 as a consequence of the COVID pandemic.

A registration trial waiver from the Chinese authorities now allows ALK to submit a Biologics Licence Application (BLA) in China without finalising the local Phase III trial. Instead, the waiver permits the relevant data in Chinese patients to be obtained as a follow-up activity, after the tablet's potential approval and launch.

ALK's Executive Vice President of Research and Development, Henrik Jacobi, said:
"*This is a big step forward for ALK's efforts to enter China with tablets . We are confident that, if approved on the basis of the already available data, this product will prove to be a valuable new treatment option for allergy specialists and house dust mite allergy sufferers in China.*"

China is already one of the world's top three markets for HDM allergy immunotherapy (AIT) treatment. With annual AIT sales estimated at more than DKK 900 million, and with an annual growth rate of more than 25 percent, China has the potential to become the world's largest HDM AIT market. For context, more than 75 million people in China are affected by HDM allergy, while just 300,000 are currently receiving treatment with AIT. ALK has had a commercial presence in China for almost 20 years, and currently offers a core HDM allergy range consisting of a diagnostic product and subcutaneous allergy immunotherapy (SCIT) – also known as allergy shots.

ACARIZAX® is ALK's HDM SLIT-tablet for the treatment of persistent moderate-to-severe HDM allergic rhinitis for 12-65 year-olds and/or for the treatment of HDM allergic asthma in 18-65 year-olds (specific indications vary across different markets). The product is also approved for paediatric use in Japan for the treatment of HDM allergic rhinitis. ACARIZAX® has been launched in multiple European countries, North America, Russia, South-East Asia, the Middle East, Australia, and Japan, and is marketed as ODACTRA® in the USA and MITICURE™ in Japan.

This announcement does not impact ALK's financial guidance for 2022.

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

Attachment

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