Regulatory filing for house dust mite allergy tablet accepted for review in China

ALK (*ALKB:DC / OMX: ALK B / AKBLF*) today announced that its Biologics License Application (BLA) for its house dust mite (HDM) sublingual allergy immunotherapy (AIT) tablet has been accepted for review by the National Medical Products Administration (NMPA) in China. The BLA, for treatment of persistent moderate-to-severe HDM allergic rhinitis in patients aged 12–65 was submitted in late December 2022.

Søren Niegel, ALK's Executive Vice President, Commercial Operations, says: *"This is an important step forward for ALK's efforts to bring new, evidence-based treatment options to the millions of people with moderate to severe allergy and their doctors in China asking for better solutions. In line with our previously communicated plans, we are investing in better allergy care with great determination in China, and we see a potential future launch of our ACARIZAX® tablet, the first AIT tablet in China, as an important contributor to our long-term growth ambitions."*

Around 100 million people in China are affected by HDM allergy, while just 500,000 are receiving allergy immunotherapy (AIT) treatment today. Total HDM AIT annual sales are already estimated at more than DKK 1 billion and China is well on its way to becoming the world's largest market for HDM AIT. More than 70% of the market is based on sublingual AIT.

ALK's current product range in China includes the SCIT product Alutard SQ® and diagnostics. To speed up the adoption of its existing offering and prepare the market ahead of the planned introduction of the HDM tablet, ALK continues to ramp up its local presence. In 2022, the local organisation was significantly expanded, while the number of hospitals and pharmacies near hospitals using ALK's products grew by more than 50% to over 500. Furthermore, ALK accelerated its efforts to educate physicians in co-operation with medical associations in China

Recently, ALK made the HDM tablet available in China's Boao Lecheng Medical Pilot Zone, where first prescriptions have been issued. ALK expects to gain valuable input from prescribers and patients in this pilot zone ahead of a nationwide launch of the tablet subject to approval by the authorities.

In early 2022, the Chinese authorities issued a regulatory waiver allowing ALK to file for approval of the HDM tablet by utilising clinical data obtained outside China and without finalising a Phase III registration trial with Chinese subjects which had to be paused in 2020 due to COVID. The waiver permits further data in Chinese patients to be obtained as a follow-up activity, after the HDM tablet's potential approval and launch. The Chinese regulatory review process is anticipated to complete in 2024 so that, subject to approval, the wider market introduction could follow shortly hereafter.

The HDM tablet is marketed as ACARIZAX® in Europe and a number of international markets, as ODACTRA® in the USA and as MITICURE™ in Japan.

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 2,700 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.