



## Marketing authorisation for ACARIZAX® issued in France

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- **House dust mites are the biggest cause of allergy in France, the world's biggest sublingual allergy immunotherapy market**
- **ACARIZAX® is the first and only sublingual allergy immunotherapy tablet approved for both house dust mite allergic rhinitis and allergic asthma**

ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF) today announced that authorities in France, the world's biggest sublingual allergy immunotherapy market, have issued a marketing authorisation for ALK's new house dust mite sublingual allergy immunotherapy tablet (SLIT-tablet), ACARIZAX®.

Jens Bager, President and CEO says: *"Following the issuance of the marketing authorisation, we can now initiate a dialogue with the authorities to make the house dust mite tablet available to doctors and patients."*

ACARIZAX® received regulatory approval in 11 European countries last year and is indicated for both allergic rhinitis and allergic asthma in adult patients not well controlled by symptom-relieving medications. ACARIZAX® was recently launched in Germany and Denmark.

Moreover, the recent, temporary suspension of production by ALK's main competitor has led to a shortage of supply for many doctors and allergy immunotherapy patients, especially in France. As the suspension continues and more allergy sufferers need to renew their prescriptions, the number of affected patients is expected to increase.

Jens Bager, President and CEO says: *"Right now, our primary concern is for the many allergy sufferers who are having their treatment interrupted and allergy protection potentially compromised, and whose health may suffer as a consequence. ALK will do all we can to help in the current situation and we are ready to support doctors and health authorities to ensure that patients continue to have treatment options available."*

In response to the situation, ALK is rapidly ramping up production of both SLIT-drops and SLIT-tablets. ALK operates a highly automated manufacturing process for its SLIT-tablets, including ACARIZAX® and grass allergy treatment GRAZAX®. Unlike production of SLIT-drops, the production of SLIT-tablets can swiftly be adapted to cope with increase in demand from the unfolding situation across Europe.

**ALK-Abelló A/S**

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### **About ALK**

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy — a treatment of the underlying cause of allergy. The company has approximately 1,900 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with MSD (known as Merck (NYSE: MRK) in the USA and Canada), Torii, Abbott and Seqirus (previously bioCSL) to commercialise sublingual allergy immunotherapy tablets in North America, Japan, Russia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and

listed on NASDAQ Copenhagen. Find more information at [www.alk.net](http://www.alk.net).

**About house dust mite allergy and ACARIZAX®**

House dust mites (HDM) are the most common cause of allergy in the world, a condition which is the subject of an unmet medical need. HDM allergy appears early in life and is present all year round. ALK estimates that one out of ten adults in Europe suffering from allergic rhinitis has a condition which is not well controlled and will experience persistent moderate to severe symptoms despite the use of symptom-relieving medications. For some of these patients, the HDM SLIT-tablet ACARIZAX® will be a relevant treatment option which can improve their quality of life and potentially modify the underlying cause of their disease.

The link between allergic rhinitis and asthma is well established. The vast majority of patients who have HDM allergic asthma also have allergic rhinitis. In addition, around 50% of asthmatic patients are reported to be sensitised to HDM.

In Europe, ACARIZAX® is indicated in adult patients (18-65 years) diagnosed by a clinical history and by a positive test for HDM sensitisation with at least one of the following conditions:

1. Persistent moderate to severe HDM allergic rhinitis despite the use of symptom-relieving medication.
2. HDM allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe HDM allergic rhinitis and where patients' asthma status has been carefully evaluated.

The product is also being developed and marketed for a number of other markets around the world in collaboration with ALK's partners, MSD (known as Merck in the USA and Canada) for North America, Torii for Japan, Abbott for Russia and Seqirus for Australia and New Zealand. The development activities have involved approximately 6,000 patients worldwide and make ALK's HDM SLIT-tablet the best documented product in the history of allergy immunotherapy.