



Company release No 16/2016

Hørsholm  
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## **License application for investigational house dust mite SLIT-tablet accepted for review by FDA**

Today, ALK's (ALKB:DC / OMX: ALK B / AKABY / AKBLF) partner for North America, MSD (known as Merck (NYSE: MRK) in the United States and Canada), announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for its house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet for review. MSD submitted the BLA, for a tablet against HDM allergy, to the FDA in February 2016.

The application to the FDA is based on results from an extensive clinical development programme that has involved approximately 4,400 patients in North America and Europe and has already seen the product approved in 11 European countries, where it is known as ACARIZAX®. The product has also been launched in Japan, where it is marketed by Torii under the brand name MITICURE™.

House dust mites are one of the most common causes of allergy, likely affecting more than 200 million people worldwide. The condition appears early in life and is present all year round.

ALK's partnership with MSD covers the development, registration and commercialisation of a portfolio of allergy immunotherapy tablets in North America.

MSD has also issued a news release, which can be found on the MSD corporate website: [www.merck.com](http://www.merck.com). This announcement does not change ALK's outlook for the financial year 2016.

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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 in the USA and Canada), Torii, Abbott and Seqirus to commercialise sublingual allergy immunotherapy tablets in North America, Japan, Russia, Southeast Asia, 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 the partnership with MSD (known as Merck in the USA and Canada) for North America**

*ALK has entered into a strategic partnership with MSD to develop, register and commercialise a portfolio of sublingual allergy immunotherapy tablets against grass pollen (GRASTEK®), ragweed (RAGWITEK®) and house dust mite allergy in the USA, Canada and Mexico. Under the agreement, ALK will receive up to DKK 1.6 billion (USD 290 million) in milestone payments from MSD, of which, approximately DKK 400 million has already been recognised in the years 2007-15. In addition, ALK is entitled to royalty payments on the net sales of the products on the North American market as well as payments for product supply. MSD will be responsible for all costs of clinical development, registration, marketing and sales of the products on the North American markets. ALK will be responsible for tablet production and supply.*

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