



ALK's partner, MSD, submits US license application for investigational house dust mite SLIT-tablet

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

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[™].

Jens Bager, President & CEO of ALK, said: "*If the investigational HDM SLIT-tablet is approved in the USA, it would allow MSD to offer a broader portfolio of SLIT-tablets to the physicians and patients following the approvals of GRASTEK[®] and RAGWITEK[®] in 2014.*"

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.

The submission of the BLA entitles ALK to a minor non-disclosed milestone payment from MSD. The payment does not change ALK's financial outlook for 2016 as the outlook is based on EBITDA before sales royalties and milestone payments from partners.

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.

About the partnership with MSD for North America

ALK has entered into a strategic partnership with MSD, known as Merck (NYSE: MRK) in the USA and Canada, 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.