



## All rights to ALK's SLIT-tablets in North America to revert to ALK from MSD

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- ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF): All rights to GRASTEK<sup>®</sup>, RAGWITEK<sup>®</sup> and investigational house dust mite SLIT-tablets for USA, Canada and Mexico to revert to ALK at no fee following a six- month transition period
- Ongoing registration processes for the investigational HDM SLIT-tablet will continue
- North America remains a major business opportunity and ALK will now undertake a full strategic analysis before deciding on a revised strategy
- Transaction has no impact on ALK's full-year outlook for 2016

Following a recent review of its strategic priorities, MSD (known as Merck (NYSE: MRK) in the United States and Canada) has informed ALK of its plans to end their partnership agreement.

As a result, all rights to ALK's sublingual allergy immunotherapy tablets (SLIT-tablets) against grass, ragweed and house dust mite (HDM) allergies for North America will revert to ALK from MSD at no fee to ALK.

### **North America still an important opportunity**

Steen Riisgaard, Chairman of ALK's Board of Directors and acting Chief Executive, said: "*The timing of this move is unexpected. However, we understand that MSD's decision was based on a prioritisation of resources. Our belief that North America represents an important opportunity for ALK's SLIT-tablets is unchanged. The sales performance over the past two years has been below expectations. Our view is that success there is likely to follow the path seen in Europe, where slow early adoption has now given way to sustained growth.*"

Sales of SLIT-tablets in Europe — from GRAZA<sup>®</sup> sales and the launch of ACARIZAX<sup>®</sup> in its first markets — grew by 97% to DKK 257 million in the first half of 2016. In the same period, ALK's income from SLIT-tablets in North America amounted to DKK 49 million. Of this, DKK 34 million was a one-off milestone payment, while the remainder came from sales royalties, R&D services and product supply.

Steen Riisgaard continued: "*Our experience in Europe suggests that there are two factors critical to success with the SLIT-tablets: approval of the HDM SLIT-tablet so the tablet range covers all three major respiratory allergies; and approval for use in the treatment of allergic asthma. We will now consider which new strategy for North America will best deliver long-term value creation for ALK. Key to this will be ensuring that the right blend of marketing skills and focus are applied to overcome the market barriers that currently exist.*"

### **A six-month transition**

Following a transition period that is expected to take six months, the rights for all three products in North America will revert to ALK by early 2017. In addition, as per the terms of the parties' agreement, MSD will complete the clinical study that is ongoing at their costs. The ongoing registration processes for the investigational HDM SLIT-tablet will continue, with increased involvement from ALK.

ALK remains fully committed to the North American markets and will mobilise resources from its North American operations and headquarters in Denmark to ensure a smooth transition in close collaboration with MSD. At the same time, ALK will undertake a full strategic review of the North American markets to determine the best options for the future commercialisation of the SLIT-tablets. Options include alternative partnerships and commercialisation by ALK's North American subsidiary.

### **Successful registrations**

The agreement between ALK and MSD, which covers the USA, Canada and Mexico, was first signed in 2007 and has

seen the successful registration of GRASTEK® and RAGWITEK® for grass and ragweed allergic rhinitis, respectively, as well as the submission of a U.S. FDA Biologics License Application for the HDM SLIT-tablet, known as ACARIZAX® in Europe.

*Registration status of ALK's SLIT-tablets in North America*

	<b>United States</b>	<b>Canada</b>
<b>GRASTEK®</b>	Launched	Launched
<b>RAGWITEK®</b>	Launched	Launched
<b>HDM SLIT-tablet</b>	Submitted (Feb 2016 U.S. FDA BLA) Possible approval in 2017	Submitted (May 2016) Possible approval in 2017

***ALK's full-year outlook unaffected***

The rights transaction does not impact ALK's full-year expectations.

ALK will publish its six-month interim report (Q2) on 16 August.

**ALK-Abelló A/S**

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***About the partnership with MSD***

*In 2007, ALK entered into a strategic partnership with MSD (then Schering Plough), known as Merck (NYSE: MRK) in the USA and Canada, to develop 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 has received approximately DKK 700 million in upfront, milestone payments and other payments. ALK was entitled to royalties on net sales as well as payments for product supply and R&D support. MSD has been responsible for all costs of clinical development and commercialisation while ALK has been responsible for production and supply of drug substance.*

***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 2,000 employees with subsidiaries, production facilities and distributors worldwide. In addition to the partnership with MSD, ALK has entered into partnership agreements with Torii, Abbott and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia and South-East Asia, 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).*

*In North America, ALK's subsidiary manufactures and sells bulk allergen extracts and allergy diagnostic kits to allergy specialists across the USA and Canada. In 2015, ALK, Inc. generated sales of approximately DKK 400 million (+12%), and recently recorded its ninth consecutive quarter of double-digit growth. ALK, Inc. employs close to 200 people in the USA and Canada.*