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ALK's partner, Merck, submits a BLA to the FDA for a marketing authorisation for ragweed AIT

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ALK's partner, Merck (known as MSD outside the USA and Canada) has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for a marketing authorisation for ragweed allergy immunotherapy tablet (AIT). ALK's partnership with Merck covers the development, registration and commercialisation of a portfolio of AITs in North America.

The application to the FDA is based on results from an extensive clinical development programme. Data from the clinical trials have demonstrated that treatment with ragweed AIT reduces patients' allergy symptoms and their concomitant use of symptom-relieving medication and that the treatment is well tolerated.

"Merck's submission is yet another milestone in ALK's efforts to globalise allergy immunotherapy and help the many allergy sufferers in need of additional treatment options. Following Merck's recent submission of a BLA for a marketing authorisation for grass AIT, there are now two products co-developed by ALK and Merck in process with the FDA. These products target the two most common pollen allergies in North America," says Jens Bager, President & CEO, ALK.

Ragweed is a significant North American seasonal, airborne allergen affecting around 30 million North Americans and is as widespread in North America as grass pollen allergy. Many patients' disease and allergy symptoms are not well-controlled and there is a significant unmet need for better treatment. The current allergy immunotherapy practice builds primarily on treatment with a special form of injections manufactured by the treating physicians on the basis of active allergen extracts. No registered allergy immunotherapy products are currently available in the USA.

The submission of the BLA entitles ALK to a milestone payment of USD 5 million from Merck. This payment has already been included in ALK's financial outlook for 2013 and consequently, this announcement does not lead ALK to change its financial outlook for the year.

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 the world leader in allergy immunotherapy – a unique treatment of the underlying cause of allergy. The company has approximately 1,850 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Merck (MSD outside the USA and Canada) and Torii to commercialise allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ OMX Copenhagen. Find more information at www.alk.net.

About the partnership with Merck in North America

ALK has entered into a strategic partnership with Merck to develop, register and commercialise a portfolio of allergy immunotherapy tablets (AITs) against grass pollen, ragweed 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 Merck, of which approximately DKK 300 million has already been recognised in the years 2007-12. 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. Merck 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.