



ALK's partner, Merck, submits a BLA to the FDA for a marketing authorisation for grass AIT (GRAZAX® in Europe)

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Copenhagen, 2013-02-01 13:00 CET (GLOBE NEWSWIRE) -- 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 grass allergy immunotherapy tablet (AIT) — a disease-modifying AIT against grass pollen allergy. The product is marketed as GRAZAX® in Europe. The 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 grass AIT reduces patients' allergy symptoms and their need for symptom-relieving medication and provides a sustained long-term effect after completion of treatment.

"Merck's submission is an important milestone in ALK's efforts to globalise allergy immunotherapy and to help the millions of allergy sufferers who need treatment," says Jens Bager, President & CEO, ALK.

It is estimated that some 30 million children and adults in North America suffer from allergy to grass pollen. 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.

ALK intends to communicate on the registration process with the U.S. health authorities when the FDA completes its initial screening of the application and on any other material developments during the process.

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 1,800 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.

