



License application for grass allergy immunotherapy tablet accepted for review by FDA

March 27, 2013

Copenhagen, 2013-03-27 13:00 CET (GLOBE NEWSWIRE) --

ALK's partner for North America, Merck (known as MSD outside the USA and Canada), today announced that the Biologics License Application (BLA) for its investigational grass allergy immunotherapy tablet (AIT) has been accepted for review by the U.S. Food and Drug Administration (FDA). The BLA, for a disease-modifying tablet against grass pollen allergy, was first submitted to the FDA in January 2013. The product is marketed as GRAZAX® in Europe.

Merck's application is based upon results from an extensive clinical development programme which demonstrates that treatment with grass AIT reduces patients' allergy symptoms and their need for symptom-relieving medication. The data also show that grass AIT provides a long-term effect for patients, which is sustained beyond the period of treatment.

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

Merck has also issued a news release, which follows in full, and which can also be found on the Merck corporate website: www.merck.com. This announcement does not change ALK's outlook for the financial year 2013.

ALK-Abelló A/S

Jens Bager
President & CEO

For further information please contact:

Jens Bager, President and CEO, tel. +45 4574 7576

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Press: Martin Barlebo, tel. +45 4574 7901, mobile +45 2064 1143

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.