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North American Phase III trial with grass allergy immunotherapy tablet meets primary endpoint. FDA filing remains planned for 2013

ALK today announces that a Phase III clinical trial of its investigational sublingual grass allergy immunotherapy tablet (AIT) met its primary efficacy endpoint. The trial was conducted by ALK's strategic partner, Merck (known as MSD outside the USA and Canada). Known as GRAZAX® in Europe, the product has been licensed by ALK to Merck for North America.

Merck initiated the trial in 2011 to evaluate the efficacy and safety of grass AIT versus placebo in the treatment of grass pollen induced allergic rhinoconjunctivitis (hay fever). The primary endpoint was the combined rhinoconjunctivitis daily symptom score (DSS) and rhinoconjunctivitis daily medication score (DMS) during the grass pollen season. The trial, which included approximately 1,500 patients, is the largest study of grass AIT to date.

The study was designed to form a pivotal part of the submission package for Merck's filing of a registration application for grass AIT with the U.S. Food and Drug Administration (FDA). Merck has informed ALK that the new data supports and confirms the planned filing of the registration application with the FDA in 2013.

Jens Bager, ALK's President and CEO, says: *"We are very excited about the fact that Merck now has sufficient data to target the planned regulatory filings for both grass and ragweed AIT with FDA in 2013. Reaching these milestones are important components in meeting our future strategic and financial objectives."*

The partnership between Merck and ALK
Merck and ALK have a strategic partnership to develop, register and commercialise a portfolio of allergy immunotherapy tablets against grass, ragweed and house dust mite allergy in the USA, Canada and Mexico. Approximately 25 million people in North America have been diagnosed as suffering from moderate-to-severe allergy to grass, ragweed or house dust mites (HDM). Many patients' disease and allergy symptoms are not well-controlled and there is a significant unmet need for better treatment.

In addition to the registration studies for grass AIT in the USA, Merck has undertaken a series of other important steps under the partnership to commercialise the tablet portfolio, including:

Ragweed: The successful completion of two Phase III clinical trials with ragweed AIT, which both consistently met the primary efficacy endpoints of reducing allergy symptoms and concomitant medication use. Recently, Merck also completed an additional safety trial in 900 patients. The results supported Merck's plans for filing of a registration application with the FDA in 2013. About 50% of the North American allergy sufferers are affected by the seasonal ragweed allergen.

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House Dust Mite (HDM): In October 2012, Merck initiated a Phase IIb clinical trial for HDM AIT (known as MITIZAX® in Europe and Japan). The purpose is to evaluate dose-related effectiveness, safety and tolerability of HDM AIT compared to placebo in the treatment of HDM-induced allergic rhinitis and rhinoconjunctivitis in adults. Additionally, Merck has recently disclosed that they are planning to initiate a Phase III clinical trial involving about 1,500 patients, which is expected to complete in 2015. Approximately 45% of allergy sufferers in North America are affected by the non-seasonal HDM allergen.

ALK's guidance
This announcement does not change ALK's financial outlook for 2012. The expected commercialisation of grass AIT and ragweed AIT products in North America is an important component in supporting ALK's overall financial ambitions to reach annual revenue of DKK 3 billion in 2015 with an operating profit (EBITDA) of 25% of revenue.

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About GRAZAX®
GRAZAX® (Grass AIT) is the world's best documented allergy immunotherapy tablet and now has data from 18 randomised, double-blind, placebo-controlled clinical studies covering nearly 6,000 patients, which shows robust evidence that GRAZAX® treats symptoms in both adults and children and targets the cause of their allergy. GRAZAX® is currently marketed by ALK as a reimbursed treatment in 16 European countries. Merck (known as MSD outside the USA and Canada) and ALK also have a co-promotion agreement for GRAZAX® in France, the second-largest immunotherapy market in the world.

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 and Torii to commercialise allergy immunotherapy tablets (AIT) in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on the NASDAQ OMX Copenhagen A/S. Find more information at www.alk-abello.com.