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ALK: Phase III studies with ragweed allergy immunotherapy tablet (AIT) meet primary endpoints

ALK announces successful outcome of two Phase III clinical studies of the new innovative ragweed tablet. Both studies met the primary efficacy endpoints and the efficacy results were consistent between the two studies.

ALK today announces that two pivotal clinical Phase III studies with its investigational sublingual Ragweed Allergy Immunotherapy Tablet (AIT) met the combined primary efficacy endpoint of reducing allergy symptoms and use of concomitant symptom relieving medication. The registration studies also showed that the treatment was well tolerated, with adverse events experienced by subjects receiving the drug similar to previous studies in adults, with no new or unexpected findings. The studies were conducted by Merck, ALK's strategic partner in North America. A total of approximately 1,350 subjects were included in the studies.

Jens Bager: *"We are very excited by the successful outcome of these important studies in the first large programme with a sublingual ragweed immunotherapy tablet. The data analysis shows robust results and we are looking forward to Merck's dialogue with the health authorities on the registration process for this new, innovative product."*

In the clinical development programme to date, two pivotal efficacy and safety studies and two safety studies have been completed for Ragweed AIT.

It is estimated that some 60 million people in North America suffer from allergies. Ragweed is a significant North American seasonal, airborne allergen affecting an estimated 50% of American allergy sufferers.

The data from the two Phase III trials are planned to be submitted for presentation at a US medical conference in 2011.

This announcement does not change ALK's outlook for the financial year 2011.

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About Ragweed AIT and the Phase III studies

The investigational Ragweed AIT treatment is designed to work by inducing a protective immune response against ragweed allergy and providing sustained prevention of allergy symptoms, treating both the symptoms and the underlying cause of the disease.

The studies were North American multicenter, randomised, placebo-controlled, double-blind, parallel-group clinical trials evaluating the efficacy and long term safety of the ragweed sublingual tablet versus placebo in the treatment of ragweed-induced rhinoconjunctivitis over a one year period based on the combined (sum of) rhinoconjunctivitis daily symptom score and rhinoconjunctivitis daily medication score. In the studies, approximately 1,350 adults received either placebo or ragweed tablet.

About the partnership with Merck, known as MSD outside the USA and Canada

In January 2007, Schering-Plough (merged with Merck in November 2009) signed an agreement with ALK to develop, register and commercialise a combined portfolio of tablet based allergy immunotherapy against grass, ragweed and house dust mite allergy in North America.

It is estimated that some 60 million people suffer from allergy in North America alone, an estimated 25 million of whom have been diagnosed as suffering from moderate to severe allergy. The majority of these patients suffer from an allergy to grass, ragweed or house dust mites, and in many cases the disease and allergy symptoms are not well-controlled. Thus there is a significant unmet need for better treatment.

At present, up to three million Americans are being treated with a special form of injection based immunotherapy preparations. The treating physicians prepare the named patient products after having received the active allergen ingredients from, for instance, ALK. No registered products for allergy immunotherapy are currently available in North America.