GRAZAX® trial in the US meets primary endpoint

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The investigational sublingual allergy immunotherapy tablet (GRAZAX®) meets primary endpoint in a study of adult subjects with a history of grass pollen allergies.

Schering-Plough Corporation, ALK's strategic partner in North America, today announced that its investigational sublingual Grass (Phleum Pratense) Allergy Immunotherapy Tablet (AIT) has met the primary endpoint in a Phase III study of adult subjects in the U.S. with a history of grass pollen induced rhinoconjunctivitis with or without asthma. The investigational Grass AIT treatment is designed to work by inducing a protective immune response against grass pollen allergy and providing sustained prevention of allergy symptoms, treating both the symptoms and the underlying cause of the disease.

The study was a U.S. multicenter, randomized, placebo-controlled, double-blind, parallel-group clinical trial evaluating the efficacy of the grass sublingual tablet versus placebo in the treatment of grass pollen-induced rhinoconjunctivitis based on the combined (sum of) rhinoconjunctivitis daily symptom score and rhinoconjunctivitis daily medication score averaged over the entire grass pollen season. In the study 439 adults were randomized to receive either placebo or grass tablet. The study met its primary endpoint.

Additionally, the adverse events experienced by subjects receiving the drug in this study were similar to previous studies in adults and include oral itching, with no new or unexpected findings.

These data are planned to be submitted for presentation at a U.S. medical conference in 2010.

This announcement does not change ALK's outlook for the financial year 2009.

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