ALK-Abelló reports phase III results from US clinical study

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Summary: The US clinical study (GT-14) with ALK-Abelló's grass tablet did not meet its primary endpoint. An analysis in a subset of patients, however, showed a positive clinical effect that is consistent with the results from the European clinical study program. Schering-Plough continues the development program and is initiating an additional one-year study, to be conducted in conjunction with the 2008 grass pollen season.

ALK-Abelló has completed a phase III clinical study (GT-14) with the tablet-based immunotherapy for grass pollen allergy in the USA. The study was designed to confirm the positive results from the European clinical study program, which led to a pan-European registration of the tablet in 2006. The GT-14 study enrolled a total of 329 patients and the primary endpoint was the reduction of patients' allergy symptoms during the grass pollen season.

The majority of patients in the active and placebo arms did not record an increase in rhinoconjunctivitis symptoms during the grass pollen season, and as a result the trial did not meet its primary endpoint. An analysis in a subset of patients, however, showed a positive clinical effect that is consistent with the results from the European clinical study program.

The safety profile was consistent with the previous European clinical studies.

Schering-Plough is initiating a one-year efficacy and safety study of the grass tablet-based immunotherapy in adults in connection with the 2008 grass pollen season. In addition, Schering-Plough will as planned initiate an efficacy and safety study of the grass tablet in children in connection with the 2008 grass pollen season.

Schering-Plough signed an agreement on January 2, 2007, with ALK-Abelló to develop and market in the United States, Canada and Mexico tablet-based immunotherapy compounds for grass pollen allergies, house dust mite allergies and ragweed allergies.

This announcement does not change ALK-Abelló's financial outlook for 2007.