House dust mite allergy immunotherapy tablet shows highly beneficial results in asthma patients (EAACI 2009)

June 8, 2009

ALK's house dust mite allergy immunotherapy tablet (AIT) has a significant positive clinical effect in asthma patients. This is the conclusion from a large Phase II/III clinical study (MT-02) presented to the scientific community today at the annual congress of the European Academy of Allergy and Clinical Immunology (EAACI) in Warsaw, Poland.

"The results of this study convincingly demonstrate that allergy immunotherapy has an effect on asthma," says Holger Mosbech, consulting physician at the Copenhagen University Hospital (Rigshospitalet), and coordinating investigator of the MT-02 study.

Patients treated with the allergy immunotherapy tablet in the highest dose achieved a 50% reduction (median value) in their use of inhaled corticosteroids compared to the amount used before treatment began. Despite the reduction of asthma medication, the patients maintained control of their asthma symptoms. The effect was highly statistically significant compared to placebo ($p=0.0036$). The median reduction of steroid use in the placebo group was 25%. The study also showed that the tablet was well tolerated and had a good safety profile.

Allergic asthma is a massive problem
House dust mite allergy is the most common indoor allergy type in the world, affecting approximately 70 million people in Europe and the USA. House dust mite allergy is also a major cause of allergic asthma.

"While treatments exist for patients with asthma, it is important to recognise that they are facing life long treatment and struggle for symptom control. The reduction in the use of asthma medicine without worsening of asthma symptoms seen in this study is remarkable. The results point out an interesting future potential for allergy immunotherapy as a part of asthma treatment," says Vibeke Backer, pulmonologist and professor at Bispebjerg Hospital, Copenhagen.

Allergy immunotherapy is the only treatment that has the potential to change the course of the allergic disease by providing sustained clinical effect and prevention of disease progression. The AIT treats the underlying cause of the allergic disease by gradually re-modulating the immune system to accept the allergen behind the allergy.

Study facts
The MT-02 study included 604 adolescent and adult patients aged from 14 years and older who were divided into four cohorts. The patients in the first three cohorts received active treatment by various doses of the house dust mite AIT. Patients in the fourth cohort all received placebo. The study was conducted over 18 months, with a minimum treatment period of 12 months, at 80 clinical centres in eight European countries. ALK will continue the clinical development programme with a view to obtaining a future European approval of the house dust mite AIT.

About ALK
ALK is a research-driven global pharmaceutical company focusing on allergy treatment, prevention and diagnosis. Our mission is to improve quality of life for people with allergy by developing pharmaceutical products that target the actual cause of allergy. ALK is the world leader in allergy immunotherapy - a unique treatment that induces a protective immune response which reduces and potentially halts the allergic reaction. Allergy immunotherapy is traditionally administered as subcutaneous injections or sublingual droplets. Our aim is to

extend the use of allergy immunotherapy by introducing convenient allergy immunotherapy tablets (AIT), thereby offering many more patients a causal allergy treatment. Following this strategy, the world's first allergy immunotherapy tablet for grass pollen allergy, GRAZAX®, was launched in Europe in 2007, and ALK has entered into a strategic partnership with Schering-Plough regarding the tablet programme in North America. ALK has approximately 1,500 employees with subsidiaries, production facilities and distributors worldwide. The company is headquartered in Hørsholm, Denmark and listed on NASDAQ OMX Copenhagen A/S. 'ALK' is an abbreviation of 'Allergological Laboratory Copenhagen (København)'. Further information is available at www.alk-abello.com.

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