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Highly positive results achieved with ALK's new tablet vaccine against house dust mite allergy

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A clinical study of ALK's tablet vaccine against house dust mite allergy showed an effect that was highly statistically significant and met its primary endpoint. The study showed a 50% reduction in the use of asthma medicine. Moreover, the study demonstrated that the tablet vaccine is well tolerated and has a good safety profile.

ALK today presents the headline results from a Phase II/III clinical study (MT-02) of the company's tablet-based vaccine against house dust mite allergy. The primary objective was to study whether patients suffering from allergic asthma caused by house dust mite allergy can reduce their use of conventional asthma medicine in the form of inhaled steroids when treated with the tablet vaccine. Patients who received the highest dose of the tablet vaccine achieved a 50% reduction (median value) in their use of inhaled steroids compared to the amount used before treatment began (baseline). The effect was highly statistically significant compared to placebo ($p=0.0036$). The study also showed that the tablet vaccine is well tolerated and has a good safety profile.

The 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 tablet, whereas 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 centers in eight European countries. ALK expects to present additional analyses and results from the study at upcoming scientific events.

ALK considers the results an important milestone in its development program, which will continue with further clinical studies with a view to obtaining a future European approval of the product. On the North American markets, ALK has licensed the product rights to its US partner, Schering-Plough.

In 2007, ALK launched the world's first registered tablet-based allergy vaccine, GRAZAX[®], against grass pollen allergy. The tablet against house dust mite allergy is the next tablet vaccine in ALK's R&D program. After grass, house dust mite allergy is the most common type of allergy worldwide.

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Jens Bager
President and CEO

About ALK

ALK is a global pharmaceutical company focusing on allergy treatment, prevention and diagnosis. Our mission is to improve quality of life for allergic people by developing pharmaceutical products that target the actual cause of allergy. ALK is the world leader in allergy vaccination (immunotherapy) – a unique treatment that induces a protective immune response which reduces and potentially halts the allergic reaction. Allergy vaccination is traditionally administered as subcutaneous injections or sublingual droplets. Our aim is to extend the use of allergy vaccination by introducing convenient, tablet-based vaccines, thereby offering many more patients a causal allergy treatment. Following this strategy, the world's first tablet-based vaccine against grass pollen allergy, GRAZAX[®], was launched in Europe in 2006, and ALK has entered into partnerships regarding the tablet programme with the Menarini Group for central and Eastern Europe and with Schering-Plough for North America. ALK has more than 1,400 employees with subsidiaries, production facilities and distributors worldwide. The company is headquartered in Hørsholm, Denmark and listed on the NASDAQ OMX Nordic Exchange Copenhagen. 'ALK' is an abbreviation of 'Allergological Laboratory Copenhagen (København)'. Further information is available at www.alk-abello.com and www.GRAZAX.com.

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