

Press release

Hørsholm
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ALK: GRAZAX[®] long-term trial highlighted as editor's choice in leading scientific journal

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Summary: Landmark results showing the long-term disease modifying effect of GRAZAX[®] are published in the American Journal of Allergy and Clinical Immunology and highlighted as the editor's choice. The trial is the only published large double-blind placebo-controlled trial to demonstrate that grass allergy immunotherapy tablets (AIT) is an efficacious treatment for grass pollen induced allergic rhinitis with sustained effect for at least two years after treatment completion.

In the March issue of the *Journal of Allergy and Clinical Immunology* (JACI – the official publication of the American Academy of Allergy, Asthma, and Immunology) a scientific article by professor Durham et al. on the sustained effect on allergy symptoms of GRAZAX[®] after completion of three years of treatment is published. JACI is by impact factor the highest-ranking scientific journal in the field of allergy.

In addition, the article is highlighted as the editor's choice. Henrik Jacobi, Executive Vice President of R&D at ALK says: "This landmark trial with GRAZAX[®] is a key achievement in the development of modern allergy immunotherapy and we are proud that the results receive this recognition by JACI. GRAZAX[®] is the only grass AIT with an approved label for long-term efficacy and a disease-modifying effect. In total, 17 randomised clinical trials involving more than 4,300 subjects have been completed and the trials consistently demonstrate the clinical benefits of this new innovative grass allergy treatment."

GRAZAX[®] was approved in Europe in 2006 and is currently marketed in all major European markets. ALK's partner, Merck (known as MSD outside the USA and Canada), holds the exclusive product rights in North America. Merck has submitted a registration application for grass AIT to Health Canada and plans to submit a registration application for grass AIT to the U.S. Food and Drug Administration in 2013.

This long-term trial is the first and largest double-blind placebo-controlled trial to demonstrate that grass allergy immunotherapy tablets (AIT) is an efficacious treatment for allergic rhinitis and that it induces long-term clinical and immunological tolerance. The newly published data demonstrates consistency throughout the three-year treatment period and the two years following treatment completion. The trial was conducted in eight European countries during 2004-2010. GRAZAX[®] is the most

extensively documented allergy immunotherapy product currently available and considerable post-marketing experience has been achieved.

GRAZAX[®] has also been shown to alleviate symptoms of asthma in children and the product is currently being investigated in the GRAZAX[®] Asthma Prevention (GAP) trial involving 800 children.

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About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is the world leader in allergy immunotherapy – a unique treatment of the underlying cause of allergy. The company has approximately 1,800 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Merck and Torii Pharmaceutical Co. Ltd. to commercialise allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on the NASDAQ OMX Copenhagen A/S. Find more information at www.alk-abello.com.