Fighting the cause of allergy



Press release

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Hørsholm, Denmark 8 June 2009 Landmark data from the European allergy congress:
Improved quality of life and sustained symptom control of GRAZAX® after completion of treatment

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The clinical benefits of ALK's allergy immunotherapy tablet (AIT) for grass allergy, GRAZAX[®], are sustained after completion of treatment. A follow-up study covering the first year after treatment demonstrates continued symptom control as well as improved quality of life in grass pollen allergic people. For the first time ever, these landmark results are presented to the scientific community today at the annual congress of the European Academy of Allergy and Clinical Immunology (EAACI 2009), in Warsaw, Poland.

"The follow-up results are exciting, as they document that the true benefit of immunotherapy, the long term effect, is obtained with GRAZAX[®]. The results are encouraging to allergic patients as they emphasize that it is worthwhile going through the continuous all year round treatment course; it pays off, not only during treatment, but also in the long run," says the study's principal investigator, professor Stephen R. Durham, National Heart and Lung Institute, Imperial College, London, UK.

Sustained relief for patients

During the first year after treatment, GRAZAX® continues to provide significant reductions in both hay fever symptoms and the patients' use of symptomatic medication. Sneezing, itchy or watery eyes and a runny, itchy or blocked nose are the most common symptoms reported by allergic rhinoconjunctivitis patients. One year after GRAZAX® treatment, these symptoms remain reduced by 25-60%.

Furthermore, the data shows that quality of life continues to be significantly improved. Through the first year after treatment, the improvement of quality of life was sustained at 23% over and above that achieved with symptomatic medications alone. This implies sustained improvements to the patients' daily practical activities, emotional well-being and sleep. These are all important parameters in this disease.

"Allergy is a massively under-diagnosed and under-treated disease. Patients experience an enormous impact on quality of life – during working hours as well as leisure time. They suffer from sleep disturbance, leading to daytime tiredness and increased absence from school and work," says Stephen R. Durham.

Major breakthrough for patients in causal allergy treatment

The results from the fist follow-up year represent a major breakthrough. ALK is the first company ever to document a sustained disease modifying effect of an AIT. Patients cannot obtain such a continued vaccination effect with traditional symptomatic medication. GRAZAX® is the first allergy tablet to treat the underlying cause of grass pollen allergy as well as the allergy symptoms.



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The pivotal GRAZAX® GT08 study is a randomized, parallel-group, double-blind, placebo-controlled, multicentre study. Patients were randomised to receive either three years of GRAZAX® treatment or placebo, followed by a two year follow-up period (the second follow-up year is currently ongoing). Throughout the study, all patients have free access to symptomatic medication.

The data form the first follow-up year of the GT08 study is based upon a full analysis set including 283 participants, with a history of grass pollen rhinoconjunctivitis uncontrolled by symptomatic medication.

The main clinical study endpoints were:

- Rhinoconjunctivitis symptom score
- Rhinoconjunctivitis medication score
- Quality of Life (QoL)

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 and www.GRAZAX.com.

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