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Five-year *GRAZAX® Asthma Prevention* (GAP) Trial Reveals Benefits of Early Treatment Intervention in Children

- **The disease modifying property of GRAZAX® (SQ® grass SLIT-tablet) resulted in long-term effect on allergic rhinoconjunctivitis (ARC) and prevented asthma symptoms, even two years after end of treatment in children with grass pollen ARC and no existing signs or symptoms of asthma**
- **Younger children had a higher probability of developing asthma. The younger the children were at treatment-start, the greater the percentage was prevented from having asthma symptoms and using asthma medication during the two-year follow-up period post discontinuation of treatment**
- **Evidence in asthma continues to build for latest generation of allergy immunotherapy treatments**

ALK (ALKB: DC / OMX: ALK B / AKABY / AKBLF) today released further analysis of data from its landmark five-year *GRAZAX® Asthma Prevention* (GAP) clinical trial in children. The analysis, which appears online in press in *The Journal of Allergy and Clinical Immunology*, shows that the benefits of GRAZAX® in prevention of asthma symptoms were even more pronounced when treatment was initiated at an earlier age.

The GAP trial, which is the largest double-blind, placebo-controlled trial ever conducted in allergy immunotherapy in a paediatric population, was initiated in 2009 to investigate the effect of ALK's sublingual grass allergy immunotherapy (SLIT) tablet, GRAZAX®, on the risk of developing asthma when compared with placebo treatment. The trial involved 812 children aged 5-12 years at 101 sites in 11 European countries and comprised a three-year treatment phase with a two-year follow-up phase.

The primary trial endpoint was the time to a first diagnosis of reversible impairment of lung function. The hypothesis was that fewer children given GRAZAX® would receive this diagnosis or that they would be diagnosed later than subjects in the placebo group.

This primary endpoint was not met and the trial indicated that an appropriate asthma diagnosis in this particular population should not be based on a single time point evaluation but rather rely on a combined clinical assessment obtained over a longer observation period, which is normally done in daily practice. However, the trial did reveal several advantages of early treatment of children with GRAZAX®. Including:

- GRAZAX® significantly reduced the proportion of children experiencing asthma symptoms or using asthma medication - an effect that was observed year round and sustained for two years after end of treatment
- The younger the children were at treatment initiation, the greater the percentage of children avoiding asthma symptoms and the need for symptomatic asthma medication during the follow-up period
- The disease modifying effect on ARC in children was verified

The GAP trial also confirmed that the safety and tolerability of GRAZAX® were favourable and in line with previous studies, with no new or unexpected findings.

Erkka Valovirta, Adjunct professor of clinical and paediatric allergology, University of Turku, Finland, said: *"The landmark GAP trial uncover valuable data about allergic asthma and the potential for preventing it with a new class of clinically proven allergy immunotherapy products such as GRAZAX®. These data illustrates the importance of early intervention with the right treatment for children who are at risk of developing this serious condition."*

Asthma affects an estimated 300 million individuals worldwide and is considered a serious global health problem affecting all age groups. It is one of the most common chronic childhood diseases and can impose a considerable burden on patients, their families, and health care systems. Allergic rhinoconjunctivitis is a recognised risk factor for asthma development.

GRAZAX® is one of a new generation of allergy immunotherapy treatments that show benefits in respiratory allergy. It reduces ARC symptoms and the need for allergy pharmacotherapy. In addition, the latest GAP data indicate that the disease modifying properties of GRAZAX® extends to prevent the development of asthma symptoms in children with grass pollen ARC. GRAZAX® is today marketed in Europe and Australia as the only product with an ARC disease modifying effect. In North America GRAZAX® is available under the brand name GRASTEK®[1].

In 2015, ALK's ACARIZAX® - a sister product to GRAZAX® used in the treatment of house dust mite allergy - became the first SLIT-tablet to be approved for use in patients with house dust mite allergic asthma in Europe. In February 2017, clinical data for ACARIZAX® led, for the first time, to the addition of allergy immunotherapy as a recommended additional treatment option in the Global Initiative for Asthma (GINA) report: *Global Strategy for Asthma Management and Prevention.*

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About GRAZAX®

GRAZAX® was approved in Europe in 2006 and is today marketed in 27 countries including Australia and North America. GRAZAX® is the world's best documented grass allergy immunotherapy product with data from 17 randomised, double-blind, placebo-controlled clinical trials, covering more than 5,600 patients. In North America GRAZAX® is available under the brand name GRASTEK®.

About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy – a treatment of the underlying cause of allergy. The company has approximately 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia, and South-East Asia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on Nasdaq Copenhagen. Find more information at www.alk.net.

[1] *GRASTEK® trademark is owned by Merck (NYSE: MRK)*