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ALK announces top-line results from the five-year landmark *GRAZAX® Asthma Prevention* (GAP) trial in children

- **The trial did not show an effect in terms of time to first diagnosis of reversible impairment of lung function.**
- **The trial demonstrated that GRAZAX® treatment significantly reduced the proportion of children experiencing asthma symptoms or using asthma medication. This effect sustained two years after end of treatment.**
- **Moreover, the trial confirmed that GRAZAX® treatment significantly reduced allergic rhinoconjunctivitis symptoms. This effect sustained two years after end of treatment.**
- **The disease-modifying effect of GRAZAX® was confirmed in children.**

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announces top-line results from the *GRAZAX® Asthma Prevention* (GAP) trial with ALK's allergy immunotherapy tablet against grass pollen allergy. The GAP trial consisted of a three-year treatment phase and a two-year follow-up phase and included 812 children aged 5–12 years at the start of the treatment phase. The primary objective was to investigate the effect of GRAZAX® compared with placebo on the risk of developing asthma.

The primary endpoint of the trial was time to first diagnosis of reversible impairment of lung function. The hypothesis was that fewer subjects receiving GRAZAX® would get this diagnosis or be diagnosed later than subjects in the placebo group. Within the five year evaluation period there was no detectable effect in terms of time to the first diagnosis of reversible impairment of lung function and hence the primary endpoint of the trial was not met.

In contrast, treatment with GRAZAX® had a positive effect on the children's asthma symptoms and use of asthma medication. The odds ratio (secondary endpoint) for experiencing asthma symptoms[1] or using asthma medication[2], at the end of the five-year evaluation period, was 0.66 ($p<0.05$) in favour of GRAZAX® treatment.

Moreover, the proportion of patients experiencing asthma symptoms or using asthma medication was significantly reduced from year 2 and onwards in the group receiving GRAZAX® treatment compared with the placebo group (with relative risk reductions ranging from 36-50%). The beneficial effect on asthma symptoms and asthma medication use was observed year-round in the two-year follow-up phase.

Thus, based on asthma symptoms and asthma medication use, a disease modifying effect was shown that sustained two years after end of treatment.

[1] Asthma symptoms included wheezing, chest tightness, shortness of breath, or cough for more than 10 consecutive days.

[2] Asthma medication included short-acting beta-2-agonist (SABA), systemic corticosteroid, inhaled corticosteroid (ICS), leukotriene receptor antagonist (LTRA), long-acting beta-2 agonist (LABA), sustained-release theophylline, or cromolyn sodium.

In addition, the GAP trial demonstrated efficacy on grass allergic rhinoconjunctivitis in the three treatment years and in two follow-up years, showing a 23-30% symptom reduction ($p<0.005$ all five years) in patients receiving GRAZAX® treatment compared with those receiving placebo (secondary endpoint). The level of symptom reduction was in line with previous trial results. All patients had access to symptom-relieving rhinoconjunctivitis medications throughout the five years of the trial. At the end of the trial, the use of this medication was recorded and patients who received GRAZAX® treatment also used significantly less rhinoconjunctivitis medications compared with those receiving placebo ($p<0.001$).

Henrik Jacobi, ALK's Executive Vice President of Research and Development says: "*With this particular trial design, we were not able to detect an effect in terms of time to the first diagnosis of reversible impairment of lung function. Nevertheless, we are very encouraged to see a clear and clinically meaningful treatment effect on asthma symptoms and on the use of asthma medication that sustains two years after end of treatment."*

He continues: "Furthermore, the trial confirms the disease modifying effect of GRAZAX® on grass pollen allergy in children. Thus, when children are treated with GRAZAX® they will not only have a beneficial effect on their nose and eye symptoms, but also a reduced risk of experiencing asthma symptoms and of using asthma medication in the years following end of treatment."

GRAZAX® was approved in Europe in 2006 and is today marketed in all major markets. GRAZAX® is the world's best documented grass allergy immunotherapy product and has data from 17 randomised, double-blind, placebo-controlled clinical trials, covering more than 5,600 patients providing evidence that GRAZAX® treats symptoms in both adults and children and targets the cause of their allergy. The product was approved in North America in 2014 where it is marketed by ALK's partner MSD (known as Merck in the USA and Canada) under the brand name GRASTEK®.

ALK-Abelló A/S

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Today, ALK hosts a conference call for analysts and investors at 6.00 p.m. (CET) at which Henrik Jacobi, EVP Research and Development will review the results and answer questions. The conference call will be audio cast on www.alk-abello.com/investor, where a presentation will be available shortly before the call begins. Participants in the audio cast are kindly requested to call in before 5.55 p.m. (CET). Danish participants should call in on tel. 7022 3500 and international participants should call in on tel. +44 (0) 20 7572 1187 or +1 646 722 4972. Please use the following Participant Pin Code: 18473806#.

About the GAP trial

The GRAZAX® Asthma Prevention *(GAP) trial was initiated by ALK in 2009 to evaluate the efficacy and safety of the grass allergy immunotherapy tablet (GRAZAX®) in children with allergic rhinoconjunctivitis. The trial was a randomised, parallel-group, double-blind, placebo-controlled, multi-national trial investigating the effect of GRAZAX® compared to placebo on the risk of developing asthma.*

812 children (5-12 years of age) from 101 sites in 11 European countries (Austria, Denmark, Finland, France, Germany, Great Britain, Norway, Poland, Spain, Sweden and Switzerland) were included in the trial. The primary criteria for inclusion in the trial were a clinical relevant history of grass pollen allergic rhinoconjunctivitis having received symptomatic treatment during the two grass pollen seasons prior to treatment start and no medical history or signs of asthma.

The trial consisted of a screening phase, a three-year treatment phase with daily treatment, and a two-year follow-up phase. To rule out asthma before randomisation, two screening visits took place. The purpose of the first screening visit was to investigate the subject eligibility in terms of all inclusion and exclusion criteria. At the second screening visit (placed in the grass pollen season), all subjects were examined according to the pre-specified asthma diagnosis. Subjects with a suspicion of asthma or diagnosed with asthma were per definition screening failures. After the end of the grass pollen season 2010, eligible subjects were randomised to GRAZAX® (N=398) or placebo (N=414) for three consecutive years. The trial continued with double-blinded follow-up for additional two years. Independently of whether asthma was diagnosed or not during the trial, all randomised subjects were to continue in the trial for five years. Subjects experiencing asthma symptoms during the trial were instructed to call the investigator for an unscheduled visit.

The asthma evaluation included four components: asthma physical examination, asthma medical history, asthma medication history, and lung-function tests.

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 1,900 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with MSD (known as Merck (NYSE: MRK) in the USA and Canada), Torii, Abbott and Seqirus (previously bioCSL) to commercialise sublingual allergy immunotherapy tablets in North America, Japan, Russia, Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ Copenhagen. Find more information at www.alk.net.