

## Successful Phase III trial for ALK's tree allergy SLIT-tablet

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced the successful outcome of a pivotal Phase III clinical trial of its tree allergy sublingual immunotherapy (SLIT) tablet, with the trial meeting its primary efficacy endpoint. The tree SLIT-tablet is important to ALK's efforts to develop a full tablet portfolio for people suffering from the most common respiratory allergies. ALK is currently the only company that has completed Phase III clinical development with a tree SLIT-tablet.

The primary endpoint of the trial was the daily total combined score, which is the sum of the allergic symptom score and the use of symptom-relieving medication, measured during the birch pollen season. Treatment with the tree SLIT-tablet reduced the total combined score (primary endpoint) by 39.6% compared to placebo. The results were highly statistically significant ( $p < 0.0001$ ). The efficacy was similar when analysing data for the entire tree pollen season (i.e. including the alder and hazel pollen seasons). The trial also showed that the treatment was well-tolerated by patients, with no new or unexpected adverse events reported compared to previous clinical trials with SLIT-tablets.

Henrik Jacobi, ALK's Executive Vice President, Research and Development, says: *"We are extremely pleased to see such a clear and clinically meaningful treatment effect of the tree allergy immunotherapy tablet. In fact, the clinical effect seen in this trial was among the most significant that we have ever seen in field studies of allergy immunotherapy, which means that we have developed a unique compound."*

He continues: *"With SLIT-tablets for house dust mite, grass, ragweed and Japanese cedar allergies already filed or marketed, these trial results represent an important step forward for ALK in completing its tablet portfolio. With these five tablets, we will be able to effectively cover more than 80% of global respiratory allergies."*

ALK initiated the Phase III clinical trial in 2016 to evaluate the efficacy and safety of the tree SLIT-tablet compared with placebo in adult and adolescent patients with birch pollen allergic rhinitis and/or conjunctivitis. The trial was a randomised, placebo-controlled, double-blind, multi-centre trial involving 634 patients aged 12-65 years in eight European countries. A preceding Phase II trial in an environmental exposure chamber showed that the tablet significantly reduced patients' symptoms in response to both birch and oak pollen compared with placebo.

Allergic rhinitis (with or without conjunctivitis) represents a global health problem affecting 10 to 25% of the population. The prevalence in the general population in Europe and North America is ~20%. In Northern and Central Europe, USA and Canada, respiratory allergies are commonly caused by allergens from the birch homologous group of trees, which also includes alder, beech, hazel and oak. ALK estimates that around 15 million Europeans have tree allergies of which ~10% are believed to have symptoms that are not well controlled by conventional symptom-relieving medications. For some of these people with uncontrolled allergies to tree pollen, ALK's tablet may become a relevant treatment option.

ALK expects to submit a European and possibly also a Canadian registration application for the tree SLIT-tablet in 2018.

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**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](http://www.alk.net).*