

Allergy experts: "Clinical effect of ALK's tree SLIT-tablet among the most significant ever seen in allergy immunotherapy trials"

- **Leading allergy researchers present Phase III data on tree SLIT-tablet at EAACI Annual Congress in Munich**
- **Birch pollen-based product shown to be effective against multiple tree allergies**
- **Effect shown to be comparable across the entire birch, alder and hazel pollen season.**

ALK today announced that leading allergy researchers at a company-sponsored symposium have been the first to be presented with the full clinical and immunological data from a recent Phase III clinical trial of its new investigational tree sublingual allergy immunotherapy (SLIT) tablet.

The symposium took place in Munich, Germany, as part of the Annual Congress of the European Academy of Allergy and Clinical Immunology (EAACI), at which clinical experts outlined the societal impact of tree pollen allergies and the potential benefits of treating patients with the tree SLIT-tablet.

Clinical endpoint achieved

The trial was initiated by ALK in 2016 to evaluate the efficacy and safety of ALK's tree SLIT-tablet compared with placebo in adult and adolescent patients with birch pollen allergic rhinitis and/or conjunctivitis, and was a randomised, placebo-controlled, double-blind, multi-centre trial involving 634 patients aged 12-65 years in eight European countries.

The initial topline analysis¹ showed that the trial met its primary endpoint for the daily total combined score (TCS) – the sum of the allergy symptom score and the use of symptom-relieving medication – during the birch pollen season. The tree SLIT-tablet reduced the TCS by 39.6% versus placebo, which was highly statistically significant ($p < 0.0001$). The effect was shown to be comparable across the entire birch, alder and hazel pollen season, spanning from early January to end June across Europe.

Explorative end-of-trial oral apple challenge in a sub-group of the trial population demonstrated that treatment with the tree SLIT-tablet also have a positive impact on pollen food syndrome – a condition experienced by the majority of patients with birch allergy, and caused by a cross-reacting allergic response to structurally related food proteins, especially in fruit and nuts.

Multiple tree pollen, one treatment

In his presentation 'Confirming efficacy beyond birch: results from the European Phase III field trial', Professor and principal investigator Tilo Biedermann of the Technical University of Munich said: "*The clinical effect seen in this trial is among the most significant seen in allergy immunotherapy field studies. It is particularly noteworthy that birch pollen allergen, when refined into the active pharmaceutical ingredient used here, is effective in treatment of symptoms caused by closely related tree pollen and induces specific antibody responses towards these.*"

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 pollen of the birch homologous group of trees, which also includes alder,

beech, hazel and oak.ⁱⁱ 10-20% of people with allergic rhinitis have a condition which is not well controlled. For some of these people with uncontrolled allergies to tree pollen, ALK's tablet may become a relevant treatment option. Tree pollen is considered one of the five most significant respiratory allergen sources and with its core European season usually lasting from at least January to June.

Proven tablet technology

Henrik Jacobi, ALK's Executive Vice President of Research and Development, said: *"The tree tablet will extend the range of ALK registered SLIT-tablets which already includes grass, house dust mite and ragweed in Europe and North America. It leverages the same well-proven technology that has shown consistent clinical results across a development program of more than 20.000 patients. The addition of the tree tablet will allow the ALK SLIT-tablet range to cover all of the world's most important respiratory allergic diseases."*

A regulatory filing for the tree SLIT-tablet in Europe is planned for 2018.

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About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,300 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

About the EAACI Congress

EAACI is Europe's largest medical association for allergy and clinical immunology. Its annual congress draws allergy experts, healthcare policy makers and science media from all over the world to network, share knowledge, and hear about the latest discoveries. The 2018 EAACI Congress is being held from 26-30 May in Munich, Germany.

ⁱ See company release: *Successful Phase III trial for ALK's tree allergy SLIT-tablet* (2017-09-14) <https://newsclient.omxgroup.com/cdsPublic/viewDisclosure.action?disclosureId=791334&lang=en>

ⁱⁱ Birch homologous group includes: *Betula verrucosa* (European white birch), *Alnus glutinosa* (alder), *Corylus avellana* (hazel), *Carpinus betulus* (hornbeam), *Quercus alba* (white oak), *Castanea sativa* (sweet chestnut), *Fagus sylvatica* (common beech). Reference: Lorenz AR et al. Int Arch Allergy Immunol. 2009;148(1):1-17.