



ALK submits registration application for tree SLIT-tablet in Europe

August 22, 2018

ALK (*ALKB:DC / OMX: ALK B / AKABY / AKBLF*) today announced that the European regulatory filing for its investigational tree pollen sublingual allergy immunotherapy (SLIT) tablet has been accepted for review by the relevant health authorities via the decentralised procedure, with Germany as the reference member state.

The European regulatory review process is anticipated to take approximately 12 months so that, subject to approval, the first market introductions could take place from late 2019.

"With SLIT-tablets for house dust mite, grass, ragweed and Japanese cedar allergies already marketed, this filing represents 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," says Carsten Hellmann, President and CEO of ALK.

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

The primary endpoint of the trial was the average daily rhinoconjunctivitis 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 effect was shown to be comparable across the entire birch, alder and hazel pollen season. 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.

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 pollen allergies of which ~10% are believed to have symptoms that are not well controlled by conventional symptom-relieving medications. If approved, ALK's tree tablet may become a relevant treatment option for some of these patients with uncontrolled allergies to tree pollen.

This announcement does not impact ALK's financial guidance for 2018.

ALK-Abelló A/S

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This information is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

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.

Attachment

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