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ALK presents Phase III data on house dust mite SLIT-tablet at EAACI Annual Congress in Copenhagen

First sublingual allergy immunotherapy tablet with robust results in allergic rhinitis and allergic asthma. Data supports European regulatory filing in 2H 2014

Today, ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) has presented key trial results on its new sublingual allergy immunotherapy tablet (SLIT-tablet) for house dust mite (HDM) respiratory allergic diseases at the 2014 Annual Congress of the European Academy of Allergy and Clinical Immunology (EAACI), in Copenhagen, Denmark.

The ALK HDM SLIT-tablet works by addressing the underlying causes of HDM respiratory allergic diseases. It is the first allergy immunotherapy product with a comprehensive clinical development programme aimed at treating both upper and lower airway manifestations of HDM-induced allergic respiratory diseases (namely allergic rhinitis and allergic asthma, respectively).

Together, the MITRA and MERIT trials involved more than 1,800 patients. The trials form part of the largest clinical development programme in the history of allergy immunotherapy, involving more than 5,000 patients from Europe, North America and Japan.

MITRA trial in allergic asthma
The MITRA trial (MT-04) was initiated by ALK in 2011 to evaluate the efficacy and safety of the HDM SLIT-tablet compared to placebo in patients with HDM-induced asthma not fully controlled with medium to high dose inhaled corticosteroid (ICS). The primary endpoint of the trial was reduction in the risk of moderate-to-severe asthma exacerbation during ICS reduction as measured by the time to the first exacerbation.

The MITRA trial met its primary clinical endpoint. Patients who received the dose of 12 SQ-HDM experienced a significant improvement in their asthma control as evident by a 34% reduction in risk of suffering a moderate-to-severe asthma exacerbation during the withdrawal of inhaled corticosteroids.

Furthermore, the risk of patients experiencing nocturnal awakenings due to their asthma was significantly reduced in the observation period immediately preceding as well as after ICS withdrawal with the 12 SQ-HDM dose.

At randomisation, 28% of patients had uncontrolled asthma, according to the Global Initiative for Asthma (GINA) control assessment criteria, despite using medium to high dose ICS. The safety profile for uncontrolled patients was consistent with that of the general population with no increased risk identified. This finding may be of high clinical significance as uncontrolled asthma is considered a contraindication to presently available allergy immunotherapy products.

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MERIT trial in allergic rhinitis

The MERIT trial was initiated by ALK in 2011 to evaluate the efficacy and safety of the HDM SLIT-tablet compared to placebo in the treatment of HDM-induced allergic rhinitis. The primary endpoint of the trial was a reduction in the combined rhinitis symptom and medication score.

Patients selected for the trial had all been diagnosed with moderate-to-severe HDM-induced allergic rhinitis and were highly symptomatic and requiring regular pharmacotherapy prior to receiving treatment. These symptoms were associated with sleep disturbance, impairment of daily activities or impairment of school or work.

The MERIT trial met its primary clinical endpoint. The median combined rhinitis symptom and medication score was reduced by 22% in patients treated with the 12 SQ-HDM dose versus placebo. Furthermore, patients experienced significantly fewer days with rhinitis exacerbation (defined as a day with severe rhinitis symptoms). The risk of experiencing a day with rhinitis exacerbation was halved, equating on average to approximately 20 fewer days annually with severe rhinitis symptoms.

The phase 2 and 3 data presented demonstrated an onset of action with the 12 SQ-HDM dose as early as 8 to14 weeks post initiation of treatment.

Both the MITRA and MERIT trials also demonstrated that the treatment was well tolerated and had a favourable safety profile.

European regulatory filing on schedule

Henrik Jacobi, Executive Vice President, Research & Development at ALK, said: “These trials show very positive results for ALK’s new SLIT-tablet in treating both manifestations of house dust mite-induced respiratory allergic diseases – allergic rhinitis and allergic asthma. They show that this new treatment could reduce allergy symptoms so that moderate-to-severe cases become mild. Based on these findings, we expect to submit a regulatory filing to the European authorities in the second half of 2014.”

Professor Pascal Demoly, Head of the Respiratory & Allergy Department at the University Hospital of Montpellier and Principal Investigator on the MERIT trial, said: “This is the first time we have seen robust data on the use of allergy immunotherapy for the treatment of both HDM allergic rhinitis and allergic asthma".

He continued: “The HDM SLIT-tablet can be an important new treatment option for doctors involved in the management of patients with HDM respiratory allergic diseases whose condition is not well controlled by existing pharmacotherapy. For patients, it offers hope of relief from the burden of chronic respiratory allergy, and a potential release from the constant need to take symptomatic medication.”

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About ALK
ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is the world leader in allergy immunotherapy – a unique treatment of the underlying cause of allergy. The company has approximately 1,800 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Merck and Torii to commercialise sublingual allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ OMX Copenhagen. Find more information at www.alk.net.

About the MITRA trial
The trial was a randomised, placebo-controlled, double-blind, multi-national, multi-centre trial involving 834 patients from 13 European countries. Patients were divided into three treatment arms. Patients from the first two groups received two different doses of the tablet, while patients in the third group received placebo. Patients were dosed once daily for up to 18 months. Additionally, all patients received treatment with ICS until the last part of the trial, when ICS usage was reduced by 50% for three months, and then completely withdrawn for another three months. The trial design and success criteria were discussed with the European Medicines Agency (EMA) as scientific advice prior to trial initiation.

About the MERIT trial
The trial was a randomised, placebo-controlled, double-blind, multi-national, multi-centre trial involving 992 patients from 12 European countries. Patients were divided into three treatment arms of equal size. Patients in the first two groups received two different doses of the tablet, while patients in the third group received placebo but had unrestricted access to symptom-relieving medication. The patients received treatment once daily for one year.

About house dust mite allergy
House dust mites are the most common cause of allergy in the world. HDM-induced allergy is estimated to affect around 90 million people in Europe, North America and Japan, and more than 100 million in China. It is estimated that up to 20% are facing moderate-to-severe symptoms. The condition appears early in life, is present all year round and patients face an elevated risk of developing asthma and other allergies.