Company release No 15/2013

Hørsholm
19 June 2013

ALK announces positive outcome of pivotal Phase III trial with new allergy immunotherapy tablet against house dust mite allergy

ALK announces positive outcome of the first of two pivotal Phase III trials with its new allergy immunotherapy tablet for the treatment of house dust mite-induced respiratory diseases. The MERIT trial meets its primary endpoint and demonstrates that the new treatment has a significant clinical effect in allergic rhinitis. The positive outcome allows for a European filing in 2014.

Today, ALK announces positive top-line results from the pivotal MERIT trial conducted with ALK's allergy immunotherapy tablet against house dust mite allergy. The results demonstrate that the treatment significantly reduces symptoms and medication use in patients with house dust mite-induced allergic rhinitis. The results were highly statistically significant ($p<0.01$).

The trial also demonstrated that the treatment was well tolerated and had a favourable safety profile.

"*The robust results of the MERIT trial represent a major step forward in the treatment of the world's most common cause of allergy estimated to affect more than 200 million people worldwide. Allergy immunotherapy tablets are an efficacious and convenient treatment for the many patients experiencing poor disease control*" says Executive Vice President Henrik Jacobi, Head of R&D at ALK.

The MERIT trial (MT-06) was initiated by ALK in 2011 to evaluate the efficacy and safety of the allergy immunotherapy tablet versus placebo in the treatment of house dust mite-induced allergic rhinitis. The primary endpoint of the trial was a reduction in the combined rhinitis symptom and medication score. The trial was a randomised, placebo-controlled, double-blind, multi-national, multi-centre trial. 992 patients from 12 European countries 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.

House dust mites are the most common cause of allergy in the world. House dust mite-induced allergy is estimated to affect around 90 million people in Europe, North America and Japan, and more than 100 million people in China. The condition appears early in life, is present all year round and patients face an elevated risk of developing asthma and other allergies. In Europe's five largest markets, around 1.25 million people have been diagnosed with persistent moderate-to-severe and uncontrolled house dust mite-induced allergic rhinitis, however, it is estimated that just a quarter of these are treated with the existing injection- or drop-based allergy immunotherapy products.

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European filing in 2014
The MERIT trial was designed to form a pivotal part of ALK's submission of a registration application in Europe. The new data allows for a filing in 2014; however, ALK will await the outcome of the on-going Phase III MITRA trial before submitting the registration application.

MITRA evaluates the efficacy and safety of the allergy immunotherapy tablet in the treatment of allergic asthma caused by house dust mites. Nearly 50% of all house dust mite allergic rhinitis patients suffer from asthma. The trial involves 834 patients and aims to demonstrate that the allergy immunotherapy tablets also reduce patients' risk of asthma exacerbations.

ALK expects to report the outcome of the MITRA trial before end of Q3 2013.

Global development programme
The MERIT and MITRA trials are part of the largest clinical development programme in the history of allergy immunotherapy, which has seen simultaneous development activities in both Europe and the world's two largest pharmaceutical markets, Japan and the USA. Once completed, this programme will have involved more than 6,000 patients.

In Japan, ALK's partner Torii Pharmaceutical Co. Ltd. is undertaking two parallel pivotal Phase II/III trials to investigate the safety and efficacy of the allergy immunotherapy tablet in the treatment of house dust mite-induced allergic rhinitis and allergic asthma, respectively.

In North America, ALK's partner Merck & Co., Inc. (known as MSD outside the USA and Canada) is currently performing a Phase IIb trial and has started preparations for a pivotal Phase III clinical trial to investigate safety and efficacy in the treatment of house dust mite-induced rhinitis/rhinoconjunctivitis in adolescents and adults.

The partnership with Merck also covers two other allergy immunotherapy tablets for grass and ragweed allergy, respectively. In Q1 2013, filings for both of these products were submitted by Merck in the USA and are currently under review by the US Food and Drug Administration.

Selected, preliminary data from the MERIT trial is expected to be presented at the ALK company-sponsored symposium on Sunday 23 June during the EAACI-WAO (European Academy of Allergy and Clinical Immunology – World Allergy Organization) Congress.

This announcement does not impact ALK's financial guidance for 2013.

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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 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.