



Company release No 16/2013

11 July 2013

## **Positive results from pivotal Phase III trial of new allergy immunotherapy tablet against house dust mite-induced allergic asthma**

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***Copenhagen, Denmark; ALK (OMX: ALK.B) announces positive outcome of the second of two pivotal Phase III trials of its new allergy immunotherapy tablet for the treatment of house dust mite-induced respiratory diseases. The MITRA<sup>1</sup> trial meets its primary endpoint and demonstrates a significant reduction in the risk of moderate-to-severe asthma exacerbations.***

Today, ALK announces positive top-line results from the pivotal Phase III MITRA trial conducted with ALK's allergy immunotherapy tablet against house dust mite-induced respiratory diseases. The results demonstrate that the treatment significantly reduces patients' risks of moderate to severe asthma exacerbations. The results were statistically significant ( $p < 0.05$ ).

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

*"House dust mite-induced respiratory diseases, such as allergic rhinitis and asthma, affect more than 200 million people worldwide. Together with the successful MERIT<sup>2</sup> trial, these results represent a major step forward in developing the first clinically documented allergy immunotherapy tablet for patients severely impacted by house dust mite-induced respiratory diseases experiencing poor control of their condition," says CEO Jens Bager, ALK.*

The MITRA trial (MT-04) was initiated by ALK in 2011 to evaluate the efficacy and safety of the allergy immunotherapy tablet compared to placebo in patients with house dust mite-induced asthma. The primary endpoint of the trial was reduction in the risk of moderate to severe asthma exacerbations during steroid reduction as measured by the time to the first exacerbation.

The trial was a randomised, placebo-controlled, double-blind, multi-centre trial involving 834 patients from 13 European countries. Patients were divided into three treatment arms. Patients in 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 inhaled corticosteroids (ICS) until the last part of the trial, where the ICS usage was reduced by 50% for three months, and then completely withdrawn for another three months.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 during a *scientific advice* prior to trial initiation.

<sup>1</sup> The MITRA trial: MITIZAX Treatment of Asthma trial

<sup>2</sup> The MERIT trial: MITIZAX Efficacy in Rhinitis Trial

House dust mites are the most common cause of allergic respiratory diseases in the world. Nearly 50% of all house dust mite-allergic rhinitis patients suffer from concomitant asthma. House dust mite-induced allergic diseases are 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 the prevalence of asthma is increasing in most countries, especially among children.

Further top-line data from the MITRA trial is expected to be presented in connection with the publication of ALK's six-month interim report (Q2) on 14 August 2013.

*"The successful outcome of the MERIT and MITRA trials keeps us on course for a European filing in 2014. It also provides positive news for our partners' parallel development programmes in North America and Japan, and increases our confidence that this innovative product will help fuel our future growth," says CEO Jens Bager, ALK.*

#### **European filing in 2014**

On 19 June 2013, ALK announced robust, positive top-line results from the MERIT trial in the treatment of house dust mite-induced allergic rhinitis. The results demonstrated that the treatment reduced both symptoms and medication use in patients with house dust mite-induced allergic rhinitis. The results were highly statistically significant ( $p < 0.01$ ).

In combination, the MITRA and the MERIT trials will be a pivotal part of ALK's submission of a registration application in Europe. ALK expects to submit the registration application in 2014.

#### **Global development programme**

The MERIT and MITRA trials are part of the largest clinical development programme in the history of allergy immunotherapy, with simultaneous development activities in 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 currently 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.

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

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**About ALK**

*ALK (OMX: ALK.B) 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](http://www.alk.net).*