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ALK completes patient recruitment in Phase III trials with MITIZAX[®]

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Today, ALK announces that all patients have been successfully recruited for two pivotal Phase III clinical trials with MITIZAX[®], the new innovative allergy immunotherapy tablet against house dust mite induced hay fever and asthma. More than 1,700 patients have now been enrolled in the trials which are expected to be completed by mid-2013.

Today, ALK announces that it has successfully completed patient recruitment for two pivotal, Phase III clinical trials with MITIZAX[®] (the so-called MERIT and MITRA trials) for the treatment of house dust mite induced hay fever and asthma.

Henrik Jacobi, Executive Vice President of R&D at ALK, says: "The two Phase III trials are part of the largest development programme ever in ALK's history and we are very proud that the recruitment of patients has been successful. MITIZAX[®] has the potential to become the first-in-class disease-modifying allergy immunotherapy tablet aimed at the most common cause of allergy and allergic asthma in the world."

House dust mite allergy affects up to 200 million people in Europe, North America, Japan and China. Approximately 50% of house dust mite allergy sufferers also have asthma.

The MERIT and MITRA trials are both Phase III, randomised, parallel-group, double-blind, placebo-controlled trials that will evaluate the efficacy and safety of MITIZAX[®] given once daily compared to placebo in the treatment of house dust mite induced allergic rhinitis and allergic asthma, respectively. The MERIT trial has now enrolled more than 900 adult patients across 99 centres in 12 European countries and the MITRA trial has enrolled more than 800 adult patients across 98 centres in 13 European countries.

Clinical development with MITIZAX[®] is currently being conducted in Europe, North America and Japan. ALK is working with Merck (known as MSD outside the United States and Canada) and Torii Pharmaceutical in North America and Japan, respectively.

ALK-Abelló A/S

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About MITIZAX[®], House Dust Mite Allergy Immunotherapy Tablet

Allergy immunotherapy is a unique treatment of the underlying cause of the allergy. The treatment induces a protective immune response which provides sustained symptom relief and reduces the risk of developing asthma.

The increasing prevalence of allergy has become a major health issue worldwide. House dust mite allergy is the most common allergy in the world, affecting up to 200 million people in Europe, North America, Japan and China.

House dust mite allergy is furthermore a major cause of allergic asthma. Asthma is a disease of diffuse airway inflammation often resulting in shortness of breath, cough, wheezing and chest tightness. The symptoms are often associated with limitations in daily activities, impairment of lung function and significant use of symptomatic medication. A distinctive characteristic of asthma is acute deteriorations (exacerbations) triggered by allergens or other factors. When tested, approximately 48% of people with asthma are sensitised to house dust mites. It is estimated that more than 30 million people in Europe alone have asthma.

ALK is currently developing an allergy immunotherapy tablet (AIT) against house dust mite induced allergic rhinitis or asthma. In Europe, the clinical programme is in Phase III and has already demonstrated promising results: A recent clinical Phase II/III trial met its primary endpoint and showed a significant reduction in the need for asthma medication. Moreover, the trial demonstrated that the tablet is convenient, well tolerated and has a good safety profile. In addition, ALK has carried out two Phase I tolerability trials in adults and children, respectively. With the two new trials, a total of 2,500 patients are included in the European development programme.

The new tablet, MITIZAX[®], is part of ALK's AIT programme which led to the launch of the world's first AIT, GRAZAX[®], for the treatment of grass pollen allergy in 2007. The AIT programme also includes tablets against ragweed and tree pollen allergy.

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 Pharmaceutical Co., Ltd. to commercialise allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on the NASDAQ OMX Copenhagen A/S. Find more information at www.alk-abello.com.