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Merck plans to initiate Phase III clinical trial with HDM AIT in North America

ALK's partner, Merck, plans to initiate the first Phase III clinical trial in North America with HDM AIT (known as MITIZAX® in Europe). Patient recruitment for the trial is expected to be initiated in 2013. The trial is expected to complete in 2015.

ALK today announces that its strategic partner, Merck (known as MSD outside the USA and Canada), is planning to advance the clinical development programme for the house dust mite allergy immunotherapy tablet (HDM AIT) by initiating a Phase III clinical trial in North America. HDM AIT is ALK's new innovative AIT against HDM-induced hay fever and asthma.

The trial is expected to include approximately 1,500 patients and will investigate the safety and efficacy of HDM AIT in the treatment of HDM-induced allergic rhinitis/rhinoconjunctivitis in children and adults. Merck anticipates that the study will initiate patient recruitment in 2013 and it is expected to complete in 2015. Further information on the trial is now available at www.clinicaltrials.gov.

Jens Bager, President and CEO of ALK, states: "*The partnership with Merck is an important part of our strategy to secure global reach for our range of modern allergy immunotherapies. The news that HDM AIT will be entering the final stage of clinical development in North America represents important progress for ALK and Merck.*"

HDM AIT 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.

The Phase III trial in North America will be part of the largest development programme in the history of allergy immunotherapy. In Europe, ALK is currently conducting two clinical Phase III trials investigating safety and efficacy of HDM AIT (MITIZAX®) in the treatment of HDM-induced allergic rhinitis and asthma, respectively. In Japan, HDM AIT has been licensed to Torii and is currently also in Phase II/III clinical development. Recently, Merck initiated a Phase IIb clinical trial for HDM AIT to evaluate dose-related effectiveness, safety and tolerability of HDM AIT. This trial is expected to enroll 120 patients and to complete in 2013.

Initiation of patient dosing in the Phase III trial in North America entitles ALK to an undisclosed milestone payment from Merck. This payment is currently expected to occur in 2013 at the earliest and consequently, this announcement does not lead ALK to change its financial outlook for the current year.

ALK-Abelló A/S

Jens Bager
President & CEO

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About HDM AIT (known as MITIZAX® in Europe)
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. HDM allergy is the most common allergy in the world, affecting approximately 90 million people in Europe, North America and Japan.

HDM 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 HDM. It is estimated that more than 30 million people in Europe alone have asthma.

ALK is currently developing an AIT against HDM-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 study met its primary endpoint and showed a significant reduction in the need for asthma medication. ALK is currently conducting two clinical Phase III trials in Europe investigating the effect of MITIZAX® in the treatment of HDM-induced allergic rhinitis and asthma, respectively. ALK's partner in Japan, Torii, is currently conducting two parallel clinical Phase II/III trials in Japan to investigate safety and efficacy of HDM AIT in the treatment of HDM-induced allergic rhinitis and asthma in a Japanese population. A total of 4,300 patients are now included in the global development programme.

The new HDM tablet 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 the partnership with Merck, known as MSD outside the USA and Canada
In January 2007, Schering-Plough (merged with Merck in November 2009) signed an agreement with ALK to develop, register and commercialise a combined portfolio of tablet based allergy immunotherapy against grass, ragweed and HDM allergy in North America.

It is estimated that some 60 million people suffer from allergy in North America alone, an estimated 25 million of whom have been diagnosed as suffering from moderate to severe allergy. The majority of these patients suffer from an allergy to grass, ragweed or HDM, and in many cases the disease and allergy symptoms are not well-controlled. Thus there is a significant unmet need for better treatment.

At present, up to three million Americans are being treated with a special form of injection based immunotherapy preparations. The treating physicians prepare the named patient products after having received the active allergen ingredients from, for instance, ALK. No registered products for allergy immunotherapy are currently available in North America.

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