



MITIZAX® enters final phase of clinical development in Japan

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ALK today announces that its strategic partner, Torii, is advancing the clinical development programme for MITIZAX® by initiating two parallel Phase II/III trials in Japan. MITIZAX® is ALK's new innovative allergy immunotherapy tablet (AIT) against house dust mite induced hay fever and asthma.

The two trials will include approximately 1,800 subjects and will investigate safety and efficacy of MITIZAX® in the treatment of house dust mite induced allergic rhinitis and asthma in a Japanese population.

Jens Bager, President and CEO of ALK, states: "*The partnership with Torii is an important part of our strategy to secure global reach for our range of modern allergy immunotherapies. The news that MITIZAX® is entering the final stage of clinical development in Japan represents important progress and establishes a clear competitive advantage for ALK and Torii.*"

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.

Norihiko Matsuo, President and Representative Director of Torii, states: "*Our partnership with ALK, established in January 2011, is meeting the expectations of both companies. We are proud of the speed of our recent progress with MITIZAX® that brings us rapidly and steadily closer to improving the lives of the many patients who suffer from allergic rhinitis and asthma as a result of house dust mite allergy.*"

The two Phase II/III trials in Japan are part of the largest development programme in the history of allergy immunotherapy. In Europe, ALK is currently conducting two similar clinical Phase III trials which will complete in 2013. In North America, MITIZAX® has been licensed to Merck (known as MSD outside the USA and Canada) and is currently in Phase II clinical development.

Initiation of patient dosing in the Phase II/III trials in Japan entitles ALK to an undisclosed milestone payment from Torii. This payment has already been included in ALK's financial outlook for 2012 and consequently, this announcement does not lead ALK to change its financial outlook for the year.

ALK-Abelló A/S

Jens Bager
President and CEO

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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 approximately 90 million people in Europe, North America and Japan.

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 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 house dust mite induced allergic rhinitis and asthma, respectively. A total of 4,300 patients are now included in the global 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 Torii Pharmaceutical Co., Ltd

Torii Pharmaceutical Co., Ltd., (Torii) established in 1921, manufactures and distributes ethical pharmaceutical products. Torii is a quoted company with its headquarters in Tokyo (TSE:4551), and has about 500 medical representatives working at 14 branch offices throughout Japan. Torii markets drugs in a number of priority therapeutic areas: renal diseases and hemodialysis including pruritus in hemodialysis patients, acute diseases including acute pancreatitis, HIV, skin diseases including atopic dermatitis, lifestyle-related diseases including gout, and allergy. Torii has been the only company in Japan that manufactures and sells allergen agents for more than 40 years. Torii's principal shareholder is Japan Tobacco Inc. Read more at www.torii.co.jp.

About the partnership with Torii

In January 2011, ALK and Torii entered into an exclusive license agreement to develop, register and commercialise ALK's house dust mite allergy immunotherapy products for asthma and allergic rhinitis in Japan, which is the world's second largest market for allergy medicine after the USA. The agreement gave Torii exclusive license rights for the development, marketing and distribution of ALK's tablet based immunotherapy product against house dust mite allergy — MITIZAX[®]. The agreement also covers an injection based immunotherapy product and diagnostic products against house dust mite allergy. Moreover, the agreement includes a research and development collaboration targeting a tablet based immunotherapy product against Japanese cedar 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 (AIT) 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.