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## **ALK makes progress with MITIZAX<sup>®</sup> in Japan and Europe**

*ALK's partner, Torii, initiates clinical development programme in Japan with MITIZAX<sup>®</sup>, the new innovative tablet against house dust mite induced hay fever and asthma. The initiation releases a milestone payment to ALK and full-year outlook is adjusted upwards. In Europe, ALK accelerates the development and initiates an additional Phase III clinical study with MITIZAX<sup>®</sup> to broaden the therapeutic use of the product. ALK is now conducting two parallel Phase III studies with 1,700 patients in a total of 17 European countries.*

ALK today announces that its strategic partner, Torii, has begun the clinical development programme with MITIZAX<sup>®</sup> and initiated a Phase I study in Japan. MITIZAX<sup>®</sup> is ALK's new innovative allergy immunotherapy tablet (AIT) against house dust mite induced hay fever and asthma. The Phase I study will include approximately 50 subjects and is intended to investigate safety and tolerability of MITIZAX<sup>®</sup> in a Japanese population.

Jens Bager, President and CEO of ALK, states: *"We are satisfied with our collaboration with Torii and we have made significant progress in bringing ALK's products forward in Japan. The initiation of the Phase I study with MITIZAX<sup>®</sup> constitutes yet another milestone in ALK's efforts to obtain global availability of our modern allergy vaccines."*

### **Development in Europe accelerated**

Furthermore, ALK today announces that it is initiating an additional Phase III study (called the MERIT study) with MITIZAX<sup>®</sup> in Europe aimed at broadening the therapeutic use of the product.

Henrik Jacobi, Executive Vice President of R&D at ALK, says: *"The MERIT study will accelerate the development of MITIZAX<sup>®</sup> and shall ensure a fast market entry and a broader therapeutic use of the vaccine. This will allow more patients to benefit from the treatment. The accelerated development is expected to significantly increase the value of MITIZAX<sup>®</sup> to patients, society and ALK".*

The MERIT study is a Phase III, randomised, parallel-group, double-blind, placebo-controlled study and is intended to enrol 900 adult subjects across 86 centres in 12 European countries. The study will evaluate efficacy and safety of MITIZAX<sup>®</sup> given once daily compared to placebo in the treatment of house dust mite induced allergic rhinitis. The study is expected to be completed in 2013.

A few weeks ago, recruitment of patients for another Phase III study (the MITRA study) with MITIZAX<sup>®</sup> was initiated. The MITRA study will evaluate the efficacy and safety of the tablet in the treatment of house dust mite induced allergic asthma. The study is intended to enrol 800 adult subjects across 105 centres in 12 European countries and is also expected to be completed in 2013.

The study initiation in Japan entitles ALK to an undisclosed milestone payment from Torii. This payment was not previously included in ALK's financial outlook for 2011 and consequently ALK now expects total revenue to exceed DKK 2.3 billion and operating profit (EBITDA) to exceed DKK 400 million (previously DKK 385 million), equivalent to an increase of approximately 40% compared to last year.

#### **ALK-Abelló A/S**

Jens Bager  
President and CEO

Contact: Jens Bager, President and CEO, tel. (+45) 4574 7576

#### **About MITIZAX<sup>®</sup>, 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 indoor 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. Moreover, the study demonstrated that the tablet is convenient, well tolerated and has a good safety profile. In addition, ALK has carried out two Phase I tolerability studies in adults and children, respectively. With the two new studies, a total of 2,500 patients are included in the development programme.*

*The new tablet, MITIZAX<sup>®</sup>, is part of ALK's AIT programme which led to the launch of the world's first AIT, GRAZAX<sup>®</sup>, 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](http://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, Alutard®, 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 1,750 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](http://www.alk-abello.com).*

**For further information, please contact:**

*Investor Relations: Per Plotnikof, tel. (+45) 4574 7527, mobile (+45) 2261 2525*

*Press: Martin Barlebo, tel. (+45) 4574 7901, mobile (+45) 2064 1143*