



ALK's partner for Japan announces trial results for house dust mite SLIT-tablet

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Based on the available data, Torii expects to submit a registration application to the authorities within the next six-to-ten months.

ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF) today announced that its partner for Japan, Torii Pharmaceutical Co., Ltd. (TSE: 4551), has completed its second of two Phase II/III trials into ALK's sublingual allergy immunotherapy tablet (SLIT-tablet) for the treatment of house dust mite (HDM)-induced respiratory diseases.

Torii initiated the trial in 2012 as a randomised, multi-centre, placebo-controlled, double-blind comparative trial, looking at both the safety and efficacy of the drug in patients with house dust mite-induced allergic asthma.

While the trial confirmed that the treatment was well tolerated by patients, with no new or unexpected findings reported, the trial did not meet the primary efficacy endpoint of showing a statistically significantly lower risk of moderate to severe asthma exacerbations when compared with patients who received placebo.

A parallel trial, investigating the safety and efficacy in HDM-induced allergic rhinitis was successfully completed in March 2014 and met its primary efficacy endpoint. In all, approximately 1,800 patients have participated in the two Japanese clinical trials.

Torii will now seek to discuss the trial results, along with relevant supportive documentation from ALK's European development programme, with the Japanese health authorities. Based on the available data, Torii expects to submit a registration application to the authorities within the next six-to-ten months.

ALK's President and CEO Jens Bager said: *"We do know from numerous trials that our SLIT-tablet treatments have delivered positive safety and efficacy results in thousands of patients across the world. We will work closely with our partner Torii to analyse these results and we remain committed to our partnership's goal — of bringing ALK's portfolio of new, innovative allergy immunotherapy treatments to patients in Japan."*

Torii's two trials were similar in design to ALK's successfully completed European trials. ALK targets a regulatory filing for the house dust mite SLIT-tablet in H2 2014 in Europe.

House dust mites are the most common cause of allergy in the world, affecting 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 patients face an elevated risk of developing asthma and other allergies.

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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 to commercialise sublingual 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.

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 haemodialysis including pruritus in haemodialysis 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 sublingual allergy immunotherapy tablet against house dust mite allergy. 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 sublingual allergy immunotherapy tablet against Japanese cedar pollen allergy.