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

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that its partner for Japan, Torii Pharmaceutical Co., Ltd. (TSE: 4551), has reported positive results from its Phase II/III trial into ALK's sublingual allergy immunotherapy tablet (SLIT-tablet) for house dust mite-induced allergic rhinitis (hay fever).

The trial met its primary efficacy endpoint by showing a significantly lower 'Total Combined Rhinitis Score' (TCRS) when compared with patients who received placebo. The trial also showed that the treatment was well tolerated and had a favourable safety profile.

ALK's President and CEO Jens Bager said: "These results mark another step on our journey towards globalising ALK's portfolio of SLIT-tablets. Our partnership with Torii continues to progress rapidly and we are getting closer to a launch of these products in the world's second largest pharmaceutical market."

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.

The trial was initiated by Torii 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 rhinitis.

A second, parallel trial, looking at safety and efficacy in house dust mite-induced allergic asthma, was initiated at the same time and is expected to report in the coming months. In all, approximately 1,800 patients participated in the two trials, the results of which will determine whether Torii will submit a New Drug Application in Japan.

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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.