



ALK's partner for Japan reports positive Phase II/III trial results for Japanese Cedar 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 a sublingual allergy immunotherapy tablet (SLIT-tablet) for Japanese cedar tree pollen allergic rhinitis (hay fever).

The trial met its primary efficacy endpoint providing statistically significant improvement in the 'Total Combined Rhinitis Score' (TCRS) compared with patients who received placebo, demonstrating that the SLIT-tablet reduced symptoms of Japanese cedar pollen allergic rhinitis. 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."

The randomised, placebo-controlled, double-blind, comparative trial, which included approximately 1,000 subjects, was initiated in 2014 to investigate the safety and efficacy of the SLIT-tablet in patients with Japanese cedar tree pollen allergic rhinitis.

Torii will now proceed with the preparations for a submission of a New Drug Application to the Japanese Ministry of Health, Labour and Welfare.

ALK-Abelló A/S

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About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy — a 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 MSD (known as Merck (NYSE: MRK) in the USA and Canada), Torii, Abbott and bioCSL to commercialise sublingual allergy immunotherapy tablets in North America, Japan, Russia, Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ 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 allergy in Japan and 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. An estimated 25-35 million people suffer from allergy caused by Japanese cedar tree pollen or

house dust mites. Japan has a higher level of diagnosed allergic rhinitis than anywhere in the world. Nevertheless, allergy immunotherapy is not yet widely used. 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.