



ALK's partner, Torii, submits registration application for the house dust mite SLIT-tablet in Japan

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ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF) today announced that its partner, Torii, has submitted a New Drug Application in Japan for ALK's house dust mite sublingual allergy immunotherapy tablet for the indication of allergic rhinitis.

ALK's partner for Japan, Torii Pharmaceutical Co. Ltd., has submitted a registration application — a New Drug Application (NDA) — to the Japanese Ministry of Health, Labour and Welfare (MHLW), for ALK's house dust mite (HDM) sublingual allergy immunotherapy tablet (SLIT-tablet).

Jens Bager, ALK's President and CEO, said: "*This regulatory submission in Japan represents a major step forward for our partnership with Torii and adds further momentum to our strategy of transforming ALK from a Europe-focused company to one with global reach. We await the outcome of the regulatory review process with interest and are confident that, if approved, this product will prove a valuable new treatment option to allergy doctors and patients in Japan.*"

ALK estimates that close to 200 million people are affected by house dust mite respiratory allergic disease in Europe, North America, Japan and China. A proportion of these patients are facing moderate to severe symptoms which are poorly controlled with current standard pharmacotherapy and there is an unmet medical need for additional treatment options.

ALK's partnership with Torii covers the development, registration and commercialisation of the HDM SLIT-tablet and a SLIT-tablet against Japanese cedar pollen allergy, which is currently in Phase II/III clinical development. It also includes collaboration on a HDM injection-based immunotherapy product and HDM diagnostic product which have recently been approved for marketing by the authorities.

The HDM SLIT-tablet is also currently under review by the European authorities. ALK submitted a registration application in November 2014 and the European regulatory process is expected to take approximately 12 months. In North America, ALK's partner Merck & Co., Inc. (known as MSD outside the USA and Canada) is currently conducting a Phase III clinical trial to investigate the safety and efficacy of the HDM SLIT-tablet in the treatment of HDM allergic rhinitis. The trial is expected to be completed in 2015 and is intended to form the basis for a registration application.

ALK intends to conduct further clinical trials with the HDM SLIT-tablet to allow access to China and other emerging markets. Additional clinical development in the coming years is expected to also include trials to support paediatric use and the prevention of allergic asthma.

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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 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 the treatment of respiratory allergic disease 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 products against house dust mite allergy and Japanese cedar pollen allergy. The agreement also covers an injection based immunotherapy product and diagnostic products against house dust mite allergy.