



## **ALK's partner, Torii, submits registration application for the cedar 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 the Japanese cedar pollen sublingual allergy immunotherapy tablet for the indication of allergic rhinitis (hay fever).

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 the Japanese cedar pollen sublingual allergy immunotherapy tablet (SLIT-tablet).

Jens Bager, ALK's President and CEO, said: *"This regulatory submission in Japan adds further momentum to our strategy of transforming ALK from a largely European 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."*

Japan 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.

*"Subject to approval, the Japanese cedar SLIT-tablet could reach the market in Japan in 2017 meaning that Torii can offer innovative products against the two most common allergies in Japan to patients whose allergy symptoms are not well-controlled despite the use of standard symptom-relieving medications,"* said Jens Bager.

ALK's partnership with Torii covers the development, registration and commercialisation of the Japanese cedar SLIT-tablet and a SLIT-tablet against house dust mite (HDM) allergy, which was launched earlier this month under the name MITICURE™. It also includes collaboration on an HDM injection-based immunotherapy product and HDM diagnostic product which have recently been approved for marketing by the authorities.

### **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 1,900 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 Seqirus (previously 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](http://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](http://www.torii.co.jp).*