

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

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that its partner for Japan, Torii Pharmaceutical Co., Ltd., has submitted an application to the Japanese Ministry of Health, Labour and Welfare, seeking to expand the use of ALK's house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet MITICURE™ to include paediatric allergic rhinitis patients.

MITICURE™, which is sold by ALK as ACARIZAX® in Europe, has been approved in Japan since 2015 for adults and adolescents aged 12-64 who suffer from house dust mite-induced allergic rhinitis. The product is included on the Japanese National Health Insurance reimbursement list.

The new application is based on results from a safety and efficacy trial involving approximately 400 patients aged 5-17 with house dust mite-induced allergic rhinitis. The randomised, multi-centre, placebo-controlled, double-blind, comparative trial met its primary endpoint, showing a statistically significant and clinically meaningful improvement in the 'Total Combined Rhinitis Score' compared with placebo, demonstrating that MITICURE™ reduced the symptoms of HDM-induced allergic rhinitis as well as patient's use of other medications. These findings were consistent with data from earlier trials involving patients aged 12-64.

Henrik Jacobi, ALK's Executive Vice President of Research and Development, said: *"House dust mites are a major cause of allergy and asthma in children and can have a major impact on their quality of life – affecting sleep patterns, school attendance and their ability to maintain an active lifestyle. These results are important because they represent specific evidence of the benefits of MITICURE™ in children, and give us further clues to the potential utility of allergy immunotherapy in treating paediatric allergic disease."*

ALK's partnership with Torii covers the development, registration and commercialisation of two SLIT-tablets for Japan. A regulatory submission for the second product, a SLIT-tablet against Japanese cedar pollen allergy, has been submitted to the Japanese Ministry of Health, Labour and Welfare and is currently undergoing regulatory review.

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**About the HDM SLIT-tablet**

*MITICURE™ is currently approved in Japan for adults and adolescents aged 12-64 years who suffer from house dust mite-induced allergic rhinitis. It is also approved in the USA and in Australia, where it is licensed by ALK to Seqirus. In Europe, where it is sold by ALK as ACARIZAX®, the product has been approved in 14 countries, many of which also include an indication for use in allergic asthma. The product is also being developed for a number of other markets around the world including Canada, Russia, South-East Asia, Turkey, the Middle East and New Zealand. Altogether, clinical development activities for the HDM SLIT-tablet have involved more than 6,000 patients worldwide.*

**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 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia, and South-East Asia, and 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).*