



## ALK's partner, Torii, gains paediatric approval for the house dust mite SLIT-tablet in Japan

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ALK ([ALKB:DC](#) / OMX: ALKB / AKABY / AKBLF) today announced that its partner for Japan, Torii, has gained approval from the Japanese Ministry of Health, Labour and Welfare, 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 ODACTRA™ in the USA and ACARIZAX® elsewhere in the world, has been available in Japan since 2015 for adults and adolescents aged 12-64 who suffer from HDM-induced allergic rhinitis. The product has also been included on Japan's National Health Insurance reimbursement list since 2015.

Henrik Jacobi, ALK's Executive Vice President, Research & Development, said: *"Since its original launch, MITICURE™ has steadily been finding favour with prescribers, and latest market reports from Japan show that the uptake has now reached encouraging levels and that our partner Torii has clear market leadership. The addition of a paediatric indication extends this innovative treatment option to an important new patient population, children, for whom the long-term effects of respiratory allergy can be particularly damaging."*

The application for paediatric use drew upon clinical data from a safety and efficacy trial involving approximately 400 patients aged 5-17 with HDM-induced allergic rhinitis. The randomised, multi-centre, placebo-controlled, double-blind, comparative trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in the 'Total Combined Rhinitis Score' compared with placebo, which showed that MITICURE™ reduced the symptoms of HDM-induced allergic rhinitis in children as well as reducing their use of other medications. The findings were in line with earlier data from trials involving older patients.

Since MITICURE™ is already on the market in Japan, no new launch is necessary and the product becomes available for paediatric use with immediate effect.

### ALK-Abelló A/S

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This information is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

#### **About the HDM SLIT-tablet**

*MITICURE™ is approved in Japan for adults and paediatric use in patients who suffer from house dust mite-induced allergic rhinitis. Around the world, it is sold as ACARIZAX®, except in the USA, where it is branded ODACTRA™. Outside Europe, the product has been approved in Japan, the USA and Canada, as well as in Australia, where it is licensed by ALK to Seqirus and Singapore, where it is licensed by ALK to Abbott. In Europe, it 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 including 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 global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,300 people worldwide and is listed on Nasdaq Copenhagen. Find more information at [www.alk.net](http://www.alk.net).*

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