



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

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ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF): Approval releases milestone payment to ALK. ALK now expects operating profit (EBITDA before special items), excluding sales royalties and any additional milestone payments from partnerships, to be in the range of DKK 350-400 million (previously DKK 250-300 million).

ALK today announced that the Japanese Ministry of Health, Labour and Welfare has approved the New Drug Application for the house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet MITICURE™.

MITICURE™ is the Japanese trade name of the HDM SLIT-tablet licensed by ALK to Torii for Japan. MITICURE™ is indicated in adults and adolescents (12-64 years) as hyposensitisation therapy (allergy immunotherapy) for the treatment of allergic rhinitis caused by house dust mites.

In parallel with the approval, Torii also announced today that it is initiating a new clinical Phase III trial to investigate the safety and efficacy of MITICURE™ in paediatric patients (five-11 years). The trial is expected to enrol approximately 400 subjects.

Jens Bager, ALK's President and CEO, said: *"The HDM SLIT-tablet — a product which is fundamental to our plans of globalising both our portfolio and our company — has now been approved in two of the three most important pharmaceutical markets in the world. Today's approval in Japan follows the European approval we received in August and once again recognises the unprecedented strength of the clinical data for this product."*

ALK's partnership with Torii covers the development, registration and commercialisation of two sublingual allergy immunotherapy tablets for Japan. MITICURE™ is the first of these products to be approved and, following today's approval, Torii will move ahead with its launch plans once a price for MITICURE™ has been set under Japan's National Health Insurance system. A regulatory submission of the second product, a SLIT-tablet against Japanese cedar pollen allergy, is currently being prepared following the successful completion of a Phase II/III clinical trial earlier this year.

The HDM SLIT-tablet was recently approved in 11 European countries where it is expected to become available in the first markets within the next six months under the brand name ACARIZAX.

The HDM SLIT-tablet is also being developed for a number of other markets around the world in collaboration with ALK's partners, MSD (known as Merck in the USA and Canada) for North America, Abbott for Russia, and bioCSL for Australia and New Zealand. These development activities have so far involved approximately 6,000 patients worldwide and make ALK's HDM SLIT-tablet the best documented product in the history of allergy immunotherapy.

The Japanese approval of MITICURE™ entitles ALK to a milestone payment from Torii. Consequently, ALK is adjusting its 2015 financial outlook upwards. The milestone payment will be booked as *Revenue from SLIT-tablets* in International Markets. ALK now expects operating profit (EBITDA before special items) excluding sales royalties and any additional milestone payments from partnerships to be in the range of DKK 350-400 million (previously DKK 250-300 million).

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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, 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.

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 to manufacture and sell allergen agents for more than 40 years. Torii's principal shareholder is Japan Tobacco Inc. Read more at www.torii.co.jp.

About house dust mite allergy

House dust mites are the most common cause of allergy in the world, a condition which is the subject of significant unmet medical need. HDM allergy appears early in life and is present all year round. In general, ALK estimates that one out of ten adults in suffering from allergic rhinitis has a condition which is not well controlled and will experience persistent moderate to severe symptoms despite the use of symptom-relieving medications. For some of these patients, the HDM SLIT-tablet will be a relevant treatment option which can improve their quality of life and potentially modify the underlying cause of their disease.

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 the highest level of diagnosed allergic rhinitis 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 for a sublingual allergy immunotherapy tablet against Japanese cedar pollen allergy.