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ALK announces FDA approval for its house dust mite sublingual allergy immunotherapy tablet (ACARIZAX® in Europe)

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that the US Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for its house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet.

The HDM SLIT-tablet is an allergen extract and, in the USA, it is indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts. The HDM SLIT-tablet is approved for use in adults 18 through 65 years of age. The HDM SLIT-tablet is marketed in Europe and Australia under the brand name ACARIZAX® and in Japan as MITICURE™.

The BLA for the HDM SLIT-tablet was originally submitted by MSD (known as Merck in the USA and Canada) in February 2016 under a partnership agreement with ALK. Since then, the partnership has ended and all North American rights to the SLIT-tablet portfolio have been repatriated to ALK following a six-month, managed handover between the two companies.

Carsten Hellmann, President and CEO of ALK, said: "*The approval of the HDM SLIT-tablet marks the beginning of a new era for ALK in the USA as we now take full control of the SLIT-tablet portfolio and integrate it into our existing US business. The coming months will see a scaling up of our US organisation so that we can market the already launched GRASTEK® and RAGWITEK®, and build our competences and launch readiness ahead of the introduction of the HDM SLIT-tablet in the USA*."

ALK's SLIT-tablets against grass pollen allergy (GRASTEK®) and ragweed pollen allergy (RAGWITEK®) were both approved by the FDA in 2014.

The approval of the HDM SLIT-tablet is not expected to have an impact on ALK's 2017 financial outlook.

ALK-Abelló A/S

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About the HDM SLIT-tablet

In the USA, ALK's HDM SLIT-tablet is approved as an allergen extract indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro *testing for IgE antibodies to* Dermatophagoides farinae *or* Dermatophagoides pteronyssinus *house dust mites, or skin testing to licensed house dust mite allergen extracts. The HDM SLIT-tablet is approved for use in adults 18 through 65 years of age. In Europe, where it is sold as ACARIZAX®, the product has been approved in 14 countries. It is also approved in Japan where it is licensed by ALK to Torii and marketed under the trade name MITICURE™ and in Australia where it is licensed by ALK to Seqirus. 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.