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ALK announces top-line results from its partner MSD's North American Phase III trial of house dust mite SLIT-tablet

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF): Trial meets primary end-point by significantly improving total combined allergic rhinitis score

Today, ALK announced that its partner, MSD (known as Merck (NYSE: MRK) in the USA and Canada), has provided to ALK top-line results from a North-American Phase III clinical trial of ALK's investigational sublingual allergy immunotherapy tablet (SLIT-tablet) for the treatment of house dust mite (HDM) allergic rhinitis.

The trial demonstrated a statistically significant improvement in the primary endpoint in favour of HDM SLIT-tablet compared with placebo. The primary endpoint of the trial was to demonstrate a reduction in the 'Total Combined Rhinitis Score' (TCRS) which is the sum of the average daily rhinitis symptom score and the average daily medication score. The trial also showed that the treatment was generally well tolerated.

ALK's CEO Jens Bager said: "*With the SLIT-tablets for grass and ragweed allergies already approved by the FDA, these Phase III clinical trial results represent an important step forward for MSD to potentially expand its allergy immunotherapy portfolio to cover one of the world's most common causes of allergy – house dust mites.*"

The trial, a randomised, multi-centre, placebo controlled, double-blind, comparative trial, was initiated by MSD in March 2014 to further investigate the safety and efficacy of the HDM SLIT-tablet in patients with HDM allergic rhinitis. It involved approximately 1,500 patients in the USA and Canada and is part of the world's largest ever allergy immunotherapy development programme, which also includes trials in Europe and Japan.

MSD has informed ALK that they now plan to discuss the data and the plans for a regulatory submission of a Biological License Application (BLA) for the HDM SLIT-tablet with the US Food and Drug Administration, the FDA. MSD also informed ALK that they will present the full trial results at a future scientific congress.

The HDM SLIT-tablet is currently undergoing regulatory reviews in Europe and Japan based on a combined clinical development programme involving more than 4,000 patients, including the completion of two positive Phase III clinical trials for the treatment of HDM allergic rhinitis and one positive Phase III trial for the treatment of HDM allergic asthma.

House dust mites are one of the most common causes of allergy in the world, affecting around 90 million people in Europe, North America and Japan, and more than 100 million people in China. The condition appears early in life, is present all year round and patients face an elevated risk of developing asthma and other allergies.

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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, 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 the partnership with MSD in North America

ALK has entered into a strategic partnership with MSD (known as Merck (NYSE: MRK) in the USA and Canada) to develop, register and commercialise a portfolio of sublingual allergy immunotherapy tablets against grass pollen, ragweed and house dust mite allergy in the USA, Canada and Mexico. Under the agreement, ALK will receive up to DKK 1.6 billion (USD 290 million) in milestone payments from MSD, of which, approximately DKK 400 million has already been recognised in the years 2007-14. In addition, ALK is entitled to royalty payments on the net sales of the products on the North American market as well as payments for product supply. MSD will be responsible for all costs of clinical development, registration, marketing and sales of the products on the North American markets. ALK will be responsible for tablet production and supply.