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House dust mite SLIT-tablet enters Phase III clinical development in North America

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ALK's (ALKB:DC / OMX: ALK B / AKABY / AKBLF) partner, Merck initiates Phase III clinical development programme in North America with the new allergy immunotherapy tablet for the treatment of house dust mite-induced respiratory diseases. The advancement triggers a milestone payment to ALK.

ALK today announces that its strategic partner, Merck (known as MSD outside the USA and Canada), is advancing the clinical development programme for the house dust mite (HDM) SLIT-tablet by initiating a Phase III clinical trial in the USA and Canada. The HDM SLIT-tablet is ALK's new allergy immunotherapy tablet for the treatment of HDM-induced respiratory diseases.

The trial is expected to include approximately 1,500 subjects and will investigate safety and efficacy of the tablet in the treatment of HDM-induced allergic rhinitis in North American patients.

Jens Bager, President and CEO of ALK, commented: *"The partnership with Merck is an important part of our strategy to bring our SLIT-tablet portfolio to patients all over the world. The news that the HDM SLIT-tablet is entering the final stage of clinical development in North America represents important progress in a market that offers a significant commercial potential."*

The HDM SLIT-tablet has the potential to become the first-in-class, disease-modifying allergy immunotherapy tablet aimed at the most common cause of allergy and allergic asthma in the world.

The Phase III trial in North America is part of the largest development programme in the history of allergy immunotherapy. In 2013, ALK successfully completed two Phase III clinical trials in Europe, the MERIT and the MITRA trials, investigating the efficacy and safety of the HDM SLIT-tablet in the treatment of HDM-induced allergic rhinitis and allergic asthma, respectively. In Japan, ALK's strategic partner, Torii, is undertaking a similar development programme and has recently announced successful outcome of a Phase II/III clinical trial into allergic rhinitis. Another Phase II/III clinical trial into allergic asthma is expected to complete in 2014.

Initiation of patient dosing in the Phase III trial in the USA and Canada entitles ALK to a milestone payment from Merck. Consequently, ALK is updating its financial outlook for 2014. The milestone payment will be booked as revenue from SLIT-Tablets in North America and ALK now expects operating profit (EBITDA) to be DKK 300-400 million (previously 225-400) before special items, income from product supply, and potential sales royalties in North America. The higher end of this range assumes two additional product development milestone payments from Merck.

ALK-Abelló A/S

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About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is the world leader in allergy immunotherapy – a unique 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 Merck and Torii to commercialise sublingual allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ OMX Copenhagen. Find more information at www.alk.net.

About the partnership with Merck in North America

ALK has entered into a strategic partnership with Merck 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 Merck, of which, approximately DKK 300 million has already been recognised in the years 2007-13. 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. Merck 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.