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ALK announces FDA approval for Merck's ragweed sublingual allergy immunotherapy tablet RAGWITEK®

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that the US Food and Drug Administration (FDA) has approved the Biologic License Application (BLA) for RAGWITEK®.

Licensed to Merck (known as MSD outside the USA and Canada) for North America by ALK, RAGWITEK® is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. RAGWITEK® is approved for use in adults 18 through 65 years of age. RAGWITEK® is not indicated for the immediate relief of allergic symptoms.

Jens Bager, ALK's President and CEO, said: "Ragweed allergy is the second most common pollen allergy in the USA. With the FDA approval of RAGWITEK®, US patients who suffer from moderate to severe ragweed allergy will now gain access to effective, convenient and well documented allergy treatment".

ALK's partnership with Merck covers the development, registration and commercialisation of a portfolio of sublingual allergy immunotherapy tablets in North America. RAGWITEK® is the second of these products to be approved by the FDA. The third tablet, the house dust mite SLIT-tablet, is in Phase III.

Jens Bager said: "Two SLIT-tablets on the US market and a third in final clinical Phase III is a major step towards commercialising sublingual allergy immunotherapy tablets globally."

The US approval of RAGWITEK® 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 up to DKK 400 million (previously 375-400) before special items, income from product supply, and potential sales royalties in North America.

ALK-Abelló A/S

ALK will be hosting an R&D and business briefing for institutional investors, equity research analysts and media in New York City on May 21, 2014. Further details will be available closer to the date. Any questions regarding this event can be directed to Janet Dally at janetdally@maidstonelifesci.com (+1 609-466-0466). Please use this link to register online: https://www.regonline.com/Alkbusinessbriefing

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About RAGWITEK®
RAGWITEK® is a SLIT-tablet for the treatment of ragweed pollen-induced allergic rhinitis and conjunctivitis. Ragweed is a weed originating from North America. Ragweed allergy is a seasonal allergy, and in North America ragweed allergy is almost as widespread as grass pollen allergy, but typically causes more – and more severe symptoms for patients. Data from five randomised, double-blind, placebo-controlled clinical trials covering approximately 2,500 patients, shows robust evidence that the tablet treats symptoms in adults and targets the cause of their allergy. RAGWITEK® is licensed to Merck (known as MSD outside the USA and Canada) for North America. In April 2014, RAGWITEK® was approved by the FDA and is expected to be marketed in the near future.

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 markets 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.