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FDA postpones Advisory Committee meeting for grass AIT tablet due to US government shutdown

ALK (ALK-B.CO / OMX:ALK B / AKABY / AKBLF) today announced that due to the US government shutdown, the US Food and Drug Administration (FDA) has temporarily postponed the Allergenic Products Advisory Committee meeting scheduled for 6 November 2013 to discuss the Biologic License Application (BLA) for the investigational grass allergy immunotherapy (AIT) tablet. The FDA has not yet confirmed a new date for the Advisory Committee meeting. ALK will provide an update when additional information becomes available.

FDA advisory committees are panels of independent experts who advise the agency as they consider regulatory decisions. Advisory committee meetings are open to the public and are common for new drug classes and/or major pharmaceutical drugs under review.

In January 2013, ALK's partner for North America, Merck (NYSE: MRK), known as MSD outside the United States and Canada, submitted the BLA to the FDA for the disease-modifying tablet against grass pollen allergy. In March 2013, ALK and Merck announced that the BLA was accepted for review by the FDA.

ALK's partnership with Merck covers the development, registration and commercialisation of a portfolio of allergy immunotherapy tablets in North America.

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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 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 allergy immunotherapy (AIT) 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 2007-12. 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.

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