



ALK updates on progress in partnership with Merck in North America

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- Merck has submitted a registration application (NDS) for Grass AIT^[1] in Canada releasing a milestone payment of USD 5 million to ALK. Full-year EBITDA outlook is consequently adjusted upwards.
- Merck is initiating additional clinical study for Grass AIT in North America. The anticipated filing date in the USA is still under assessment.
- The results of two Phase III studies on Ragweed AIT anticipated to be available in Q3 2011.

Grass AIT regulatory submission in Canada

Merck has informed ALK that it has submitted a registration application (NDS) for the Grass Allergy Immunotherapy Tablet (AIT) in Canada. ALK expects Merck to launch Grass AIT in Canada after regulatory approval of the NDS.

The submission to the Canadian authorities entitles ALK to a milestone payment of USD 5 million from Merck. This payment was not previously included in ALK's financial outlook for 2011 and consequently ALK now expects operating profit (EBITDA) to amount to DKK 385 million (from previously DKK 360 million), equivalent to an increase of 34% compared to last year.

Rupert Vessey, Senior Vice President and Head of Respiratory and Immunology at Merck Research Laboratories commented: *"Merck is pleased that a regulatory filing has been made in Canada as this is the first regulatory filing in North America for this innovative new class of drugs."*

Update on Grass AIT in the USA

Merck will continue to work with the US health authorities, the Food and Drug Administration (FDA) regarding the registration process for Grass AIT in the USA; however, based on current feedback from the FDA, Merck is initiating an additional clinical study with Grass AIT in order to provide as robust a submission package as possible.

The new study is planned to be a North American Phase III, multicenter, randomised, placebo-controlled, double-blind, parallel-group clinical trial evaluating the efficacy of Grass AIT versus placebo in the treatment of grass pollen-induced rhinoconjunctivitis in 1,500 subjects. Screening of subjects for the study will be initiated in Q3 2011. Further information is posted at www.clinicaltrials.gov. Merck anticipates that the study will be completed in the fall of 2012.

The anticipated filing date for Grass AIT in the USA is still under assessment by Merck and the FDA.

Jens Bager, President and CEO of ALK, says: *"We are very pleased that Merck has submitted a registration application for Grass AIT in Canada and that Merck is initiating an additional clinical study in North America which will be the largest study ever conducted with AIT. This demonstrates Merck's strong commitment to introduce AIT in North America. ALK and Merck have a close and committed partnership and intensive work is being carried out to ensure the success of the AIT development programmes in North America."*

Results from ragweed AIT trials expected in Q3 2011

In Q3 2011, ALK expects to receive and disclose the outcome of two large Phase III clinical trials to assess the safety and efficacy of the Ragweed AIT tablet. ALK anticipates the results of the studies to be presented by Merck at a medical congress later in 2011.

ALK-Abelló A/S

Jens Bager
President and CEO

Call tel. +45 20 64 11 43 to contact Jens Bager, President and CEO, Flemming Pedersen, EVP and CFO or Henrik Jacobi, EVP Research & Development for further information.

Investor Relations: Per Plotnikof, tel. +45 45 74 75 27, mobile +45 22 61 25 25

Press: Martin Barlebo, tel. +45 45 74 79 01, mobile +45 20 64 11 43

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 1,700 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Merck and Torii Pharmaceutical Co. Ltd. to commercialise allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on the NASDAQ OMX Copenhagen A/S. Find more information at www.alk-abello.com.

About Grass AIT (GRAZAX®) development programme

The clinical development programme for Grass AIT is the largest development programme ever carried out with an allergy immunotherapy product. In the USA and Europe, a total of 15 randomised, double-blind, placebo-controlled clinical studies of Grass AIT have been conducted including a total of 3,744 patients. Grass AIT has been approved in the EU since 2006.

About the partnership with Merck

In January 2007 Schering-Plough (merged with Merck in November 2009) signed an agreement with ALK to develop, register and commercialise a combined portfolio of tablet based allergy vaccines (AIT) for grass, ragweed and house dust mite allergy in North America. It is estimated that some 60 million people suffer from allergy in North America alone, an estimated 25 million of whom have been diagnosed as suffering from moderate to severe allergy. The majority of these patients suffer from an allergy to grass, ragweed or house dust mites, and in many cases the disease and allergy symptoms are not well-controlled. Thus there is a significant unmet need for better treatment. At present, up to 3 million Americans are being treated with a special form of injection based vaccine preparations. The treating physicians prepare the named patient products after having received the active allergen ingredients from, for instance, ALK. No registered products for allergy immunotherapy are currently available in North America.

[\[1\]](#) Marketed under the brand name of GRAZAX® by ALK in Europe