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ALK announces FDA approval for Merck's grass sublingual allergy immunotherapy tablet GRASTEK® (GRAZAX®)

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 Merck's grass sublingual allergy immunotherapy (SLIT) tablet GRASTEK®.

GRASTEK® is the US trade name of the grass SLIT-tablet which is licensed to Merck (known as MSD outside the USA and Canada) for North America by ALK, and marketed in Europe under the brand name GRAZAX®.

GRASTEK® is an allergen extract. In the USA, GRASTEK® is indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. GRASTEK® is approved for use in persons 5 through 65 years of age. GRASTEK® is not indicated for the immediate relief of allergic symptoms.

Jens Bager, President and CEO of ALK, said: "With the FDA approval of GRASTEK®/GRAZAX®, US patients who suffer from moderate to severe grass allergy will now gain access to effective, convenient and well documented allergy treatment."

He continued: "Merck is now able to launch the first of ALK's tablets in the USA – the world's largest pharmaceutical market. This is another major step on our journey towards commercialising our portfolio of SLIT-tablets globally."

ALK's partnership with Merck covers the development, registration and commercialisation of a portfolio of sublingual allergy immunotherapy tablets in North America. GRASTEK® is the first of these products to be approved by the FDA and, following today's approval, Merck is expected to move ahead with its launch plans.

The FDA is currently also reviewing Merck's BLA for a SLIT-tablet against ragweed allergy (RAGWITEK™). Following a positive recommendation from the FDA's Advisory Committee in January, a decision by the FDA is expected in Q2 2014.

The US approval of GRASTEK® 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 375-400 million (previously 300-400) before special items, income from product supply, and potential sales royalties in North America. The higher end of this range assumes one additional product development milestone payment from Merck.

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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).

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About GRASTEK®/GRAZAX®

GRASTEK®/GRAZAX® is a SLIT-tablet for the treatment of grass pollen-induced allergic rhinitis and conjunctivitis. Data from 18 randomised, double-blind, placebo-controlled clinical trials covering over 6,000 patients, shows robust evidence that the tablet treats symptoms in both adults and children and targets the cause of their allergy. The data also shows that the reduction in allergy symptoms and use of medication is sustained after completion of treatment. GRAZAX® was approved in Europe in 2006 and is currently marketed in 16 European countries. GRAZAX® is licensed to Merck (known as MSD outside the USA and Canada) for North America and will be marketed under the trade name GRASTEK®. In the beginning of 2014, GRASTEK® was launched in Canada. In April 2014, GRASTEK® 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.