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Hørsholm
12 December 2013

FDA Advisory Committee meeting unanimously recommends approval of GRASTEK™ (GRAZAX®)

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that the Allergenic Products Advisory Committee of the US Food and Drug Administration (FDA) has voted unanimously that the available data support the efficacy and safety of Merck's GRASTEK™ in patients aged five to 65 years. The committee further recommended that adrenaline auto-injectors should be made available for patients at home.

GRASTEK™ is the proposed US trade name of the grass sublingual allergy immunotherapy tablet, 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®.

The FDA is currently reviewing Merck's Biologic License Application (BLA) for GRASTEK™ for the treatment of grass pollen induced allergic rhinitis, with or without conjunctivitis, in adults and children of five years and older.

Jens Bager, ALK's President and CEO, said: "ALK welcomes the FDA Advisory Committee's conclusion, which represents another important step towards bringing this innovative new treatment to US patients."

Although not binding, the FDA will consider the committee's recommendation as it completes its review of the BLA for GRASTEK™, a process that is expected to be concluded during the first half of 2014.

ALK-Abelló A/S

Jens Bager
President & CEO

Conference call
Tomorrow at 8.00 a.m. (CET), ALK will host a conference call for analysts and investors. The conference call will be audio cast on www.alk-abello.com/investor. Participants in the audio cast are kindly requested to call in before 7.55 a.m. (CET). Danish participants should call in on tel. +45 7026 5040 *or* +45 7027 9009 *and international participants should call in on tel.* +44 208 817 9301*.*

For further information please contact:

Jens Bager, President and CEO, tel. +45 4574 7576

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Press: Martin Barlebo, tel. +45 4574 7901, mobile +45 2064 1143

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 2007-12. 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.

ALK-Abelló A/S – Bøge Allé 6-8 – DK-2970 Hørsholm – Denmark – www.alk.net
Tel +45 4574 7576 – Fax +45 4574 8607 – CVR No 63 71 79 16