Company release No 2/2014

Hørsholm
24 January 2014

ALK announces posting of briefing documents for FDA Advisory Committee meeting on the ragweed sublingual tablet

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that the US Food and Drug Administration (FDA) has posted briefing documents for the Allergenic Products Advisory Committee meeting on 28 January to review Merck's Biologic License Application (BLA) for the investigational ragweed sublingual allergy immunotherapy tablet.

The briefing materials for the Allergenic Products Advisory Committee meeting can be found on the FDA website at:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/ucm379932.htm

At the meeting, the Committee will be asked:

- Whether the available data support the safety and the efficacy of the product in persons of 18 years of age and older
- To discuss recommendations regarding the need, if any, for additional trials

In March 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 investigational sublingual tablet against ragweed allergy, which has the proposed trade name of RAGWITEK™. In May, ALK and Merck announced that the BLA was accepted for review by the FDA. In December, it was announced that an FDA Advisory Committee would review the application.

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.

Under US Freedom of Information legislation, Advisory Committee materials must be made available for public inspection, usually no later than two business days before the meeting takes place.

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

Conference call
On 29 January 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 dial in on +45 7026 5040 or +45 7027 9009 and international participants should dial in on +44 208 817 9301.

ALK-Abelló A/S

Jens Bager
President & CEO

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

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
Media: 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 2007-13. 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.