

Company release No 16/2015

ALK obtains European approval for its house dust mite sublingual allergy Hørsholm 31 August 2015 immunotherapy tablet against allergic rhinitis and allergic asthma Page 1/2 ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that it has successfully completed the registration procedure for its house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet in 11 European countries¹. The HDM SLIT-tablet is indicated in adult patients (18-65 years) diagnosed by a clinical history and by a positive test for HDM sensitisation with at least one of the following conditions: 1) Persistent moderate to severe HDM allergic rhinitis despite the use of symptomrelieving medication 2) HDM allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe HDM allergic rhinitis and where patients' asthma status has been carefully evaluated. Jens Bager, President and CEO of ALK says: "The approval of our HDM SLIT-tablet represents a major landmark for ALK and is the result of 10 years of research and development work. For the first time, patients in Europe will now have access to an effective, well documented and home-based treatment for house dust mite allergy." He continues: "This new treatment option improves quality of life for patients with house dust mite allergic rhinitis that is not well controlled despite the use of symptom-relieving medications. Moreover, we are very pleased to see that the product was recognised by the authorities for its benefits in patients with allergic asthma. This highlights the HDM SLIT-tablet as an effective treatment for both allergic rhinitis and asthma." Following today's completion of the registration procedure, ALK expects the product to become available in the first European markets within the next six months, once local market access negotiations have been completed. House dust mites are the most common cause of allergy in the world, a condition which is the subject of an unmet medical need. HDM allergy appears early in life and is present all year round. ALK estimates that one out of ten adults in Europe suffering from allergic rhinitis has a condition which is not well controlled and will experience persistent moderate to severe symptoms despite the use of symptom-relieving medications. For some of these patients, the HDM SLIT-tablet will be a relevant treatment option which can improve their quality of life and potentially modify the underlying cause of their disease. The link between allergic rhinitis and asthma is well established. The vast majority of patients who have HDM allergic asthma also have allergic rhinitis. In addition, around 50% of asthmatic patients are reported to be sensitised to HDM.

¹ Austria, Czech Republic, Denmark, Finland, France, Germany, Italy, Norway, Poland, Slovakia and Sweden



Page 2/2 The HDM SLIT-tablet is also being developed for a number of other markets around the world in collaboration with ALK's partners, MSD (known as Merck in the USA and Canada) for North America, Torii for Japan, Abbott for Russia and bioCSL for Australia and New Zealand. These development activities have involved approximately 6,000 patients worldwide and make ALK's HDM SLIT-tablet the best documented product in the history of allergy immunotherapy.

ALK-Abelló A/S

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: Jeppe Ilkjær, tel. +45 7877 4532, mobile + 45 3050 2014

Conference call

Today at 2.00 p.m. (CEST), ALK will host a conference call for analysts and investors where Henrik Jacobi, EVP Research & Development, will review the label of the HDM SLIT-tablet. The conference call will be audio cast on <u>www.alk-abello.com/investor</u>. Participants in the audio cast are kindly requested to call in before 1.55 p.m. (CEST). Danish participants should call in on tel. +45 7022 3500 and international participants should call in on tel. +44 207 572 1187 or +1 646 722 4972. Please use the following Participant Pin Code: 24344932#.

About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy – a 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 MSD (known as Merck (NYSE: MRK) in the USA and Canada), Torii, Abbott and bioCSL to commercialise sublingual allergy immunotherapy tablets in North America, Japan, Russia, Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ Copenhagen. Find more information at www.alk.net.