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ALK submits registration application for house dust mite SLIT-tablet in Europe

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that a registration application for the house dust mite sublingual allergy immunotherapy tablet has been submitted in Europe. House dust mites are the most common cause of respiratory allergic disease, affecting an estimated 35 million adult Europeans of whom more than 3 million are poorly controlled with current standard pharmacotherapy.

Today, ALK's regulatory filing for the house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet has been accepted for review by the European health authorities via the Decentralised Procedure with Germany as the Reference Member State.

"*The filing is a landmark event as the HDM SLIT-tablet is ALK's most important product candidate and the first of its kind in Europe. House dust mites are the most common cause of respiratory allergic disease. The condition appears early in life, it is present all year round, and involves both allergic rhinitis and allergic asthma. Our ambition is that patients, who are in poor control of their disease despite the use of symptom-relieving medication, are relieved from the burden of this chronic disease*," says Jens Bager, President and CEO of ALK.

The regulatory review process is expected to take around 12 months, which means that, subject to approval, the first launches could possibly take place in 2016.

The European market
House dust mite allergy is estimated to affect 35 million adult Europeans, of whom more than 3 million are poorly controlled and experience persistent moderate to severe symptoms despite the use of symptom-relieving medication[1,2]. An additional 1 million children and adolescents are estimated to be in the same situation[1,2,3]. ALK estimates that roughly 50% of these patients live in countries where they have no or very limited access to allergy immunotherapy treatment. For the sufferers and society as a whole, the impact of respiratory allergic disease is significant. Almost 70% of patients with allergic rhinitis feel that their condition limits their way of life and 43% of patients suffering from allergic rhinitis and allergic asthma have difficulties sleeping[4].

Supporting clinical data
ALK's regulatory filing is supported by a clinical development programme involving approximately 3,000 patients. Data from the clinical trials demonstrated efficacy in both HDM allergic asthma and HDM allergic rhinitis.

The pivotal Phase III MITRA trial in HDM allergic asthma demonstrated that the tablet significantly reduced patients' risks of moderate or severe asthma exacerbations. Measured as a hazard ratio, patients treated with the 12 SQ-HDM dose experienced a 34% reduction in the risk of suffering moderate or severe asthma exacerbations compared with placebo treated patients during reduction of inhaled corticosteroids. This included a 36% reduction in the patients' risk of experiencing nocturnal awakenings and/or increased daytime symptoms due to their asthma[5].

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

The pivotal Phase III MERIT trial in HDM allergic rhinitis involved patients who were highly symptomatic despite regular use of pharmacotherapy. The trial demonstrated that the tablet significantly reduced patients' rhinitis symptoms and medication use. Patients treated with the 12 SQ-HDM dose experienced a 22% reduction in the median combined symptom and medication score compared with the placebo group. This effect represents an additional benefit on top of the effect provided by pharmacotherapy since all treatment groups had free access to guideline-recommended pharmacotherapy during the entire trial. Moreover, the treatment reduced the patients' risk of experiencing days with rhinitis exacerbations by 50% (defined as a day impacted by severe allergic rhinitis symptoms)[6].

Both the MITRA and MERIT trials demonstrated that the treatment was well tolerated.

Global development programme
The HDM SLIT-tablet is also in late-stage clinical development in North America and Japan. The joint development activities in Europe, North America and Japan form the largest clinical development programme in the history of allergy immunotherapy.

In North America, ALK's partner Merck & Co., Inc. (known as MSD outside the USA and Canada) is currently conducting a Phase III clinical trial to investigate the safety and efficacy of the HDM SLIT-tablet in the treatment of HDM allergic rhinitis. The trial is expected to be completed in 2015 and is intended to form the basis for a registration application.

In Japan, ALK's partner Torii Pharmaceutical Co., Ltd. is currently preparing to submit a registration application within the next 3-5 months for the HDM SLIT-tablet. The application is based on Japanese Phase III data that demonstrated efficacy in HDM allergic rhinitis. Subject to approval, the HDM SLIT-tablet could reach the market in Japan in 2016.

ALK intends to conduct further clinical trials with the HDM SLIT-tablet to allow access to China and other emerging markets. Additional clinical development in the coming years is expected to also include trials to support paediatric use and the prevention of allergic asthma. Once completed, the programme is expected to have involved more than 8,000 patients.

ALK estimates that close to 200 million people are affected by house dust mite respiratory allergic disease in Europe, North America, Japan and China. A proportion of these patients are facing moderate to severe symptoms which are poorly controlled with current standard pharmacotherapy and there is an unmet medical need for additional treatment options.

This announcement does not impact ALK's financial guidance for 2014.

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
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 Copenhagen. Find more information at www.alk.net.

References:

1. *Bauchau V and Durham SR. Eur Respir J 2004; 24: 758–764*
2. *Canonica GW et al. Allergy 2007: **62**(Suppl. 85): 17–25*
3. *EuroStat 2014: epp.eurostat.ec.europa.eu*
4. *Valovirta E, ed. EFA book on respiratory allergies. Brussels: European Federation of Allergy and Airways Diseases Patients' Associations, 2011. Available at http://www.efanet.org/wp-content/documents/EFABookonRespiratoryAllergiesFINAL.pdf*
5. *Data on file ALK: MITRA (MT-04) Integrated Clinical Trial Report*
6. *Data on file ALK: MERIT (MT-06) Integrated Clinical Trial Report*

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