ALK's ACARIZAX® data results in significant change to the GINA asthma management strategy: Sublingual allergy immunotherapy (SLIT) recommended as a treatment option in patients with house dust mite allergic asthma

February 27, 2017

Copenhagen, 2017-02-27 15:12 CET (GLOBE NEWSWIRE) --

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that for the first time, allergy immunotherapy is now recommended as a treatment option in the Global Initiative for Asthma (GINA) report: *Global Strategy for Asthma Management and Prevention.* This global strategy is a widely recognised practical resource developed to guide healthcare professionals and policy makers, and represents the latest clinical evidence and medical practice for the treatment and management of asthma. The strategy is updated annually based on review of recent scientific literature by an international panel of experts on the GINA Science Committee.

The 2017 update, which includes new information regarding the use of allergy immunotherapy, has just been released and features the following addition to steps 3 and 4 of GINA's recommended stepwise treatment of asthma in adult house dust mite (HDM) sensitive patients:

Consider adding SLIT (sublingual allergy immunotherapy) in adult HDM sensitive patients with allergic rhinitis who have exacerbations despite ICS (inhaled corticosteroids), provided FEV1 is > 70% of predicted lung function.[1)]

This change draws upon recently published results from ALK's Phase III clinical trial evaluating the treatment of HDM allergic asthma with the HDM SLIT-tablet, ACARIZAX® in *The Journal of the American Medical Association* (JAMA).[2)]

Henrik Jacobi, Executive Vice President of Research & Development at ALK, said: *"We are extremely pleased to see the recognition of ACARIZAX® clinical evidence in the management of asthma. This confirms our long-held conviction that allergy immunotherapy has an important role to play in the treatment of allergic asthma, a belief confirmed by the unprecedented clinical development programme for ACARIZAX®, currently the only HDM SLIT-tablet indicated for use in patients with house dust mite allergic asthma that is not well controlled."*

House dust mite allergy and asthma often coexist. More than half of asthmatic patients have been reported to have house dust mite sensitisation.

He continued: *"ALK is committed to gathering further evidence to support the wider recognition of allergy immunotherapy as a treatment option for asthma, and to investigating the potential role for allergy immunotherapy in preventing the onset of asthma."*

Professor J. Christian Virchow, of the University of Rostock and lead author of the recently published paper in JAMA says: *"This is very encouraging. I am pleased to see findings from this important trial translated into clinical guidelines. This underlines the importance of performing robust evidence based trials in allergy immunotherapy."*

ACARIZAX® is currently approved for the treatment in HDM allergic asthma in 12 European countries and Australia.

ALK-Abelló A/S

For further information please contact:
Media: Jeppe Ilkjær, tel. +45 7877 4532, mobile +45 3050 2014
Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

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 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia, and South-East Asia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on Nasdaq Copenhagen. Find more information at www.alk.net.

About house dust mite allergy and ACARIZAX®
House dust mites (HDM) are the most common cause of allergy in the world. HDM allergy is estimated to affect around 90 million people in Europe, North America and Japan, and more than 100 million in China. It is estimated that one in 10 adults with allergic rhinitis are poorly controlled with current standard therapies. The condition appears early in life, is present all year round and patients face an elevated risk of developing asthma and other allergies. For some of these patients, the HDM SLIT-tablet is a relevant treatment option which can improve their quality of life and potentially modify the underlying cause of their disease.

ALK's HDM SLIT-tablet is a treatment for house dust mite-induced allergic rhinitis (AR) with or without conjunctivitis and allergic asthma (AA) that is not well controlled by symptomatic medication. In Europe, where it is marketed as ACARIZAX®, the product has been approved in 14 countries for the treatment of AR, 12 of which also include the HDM AA indication. It is also approved in Japan for AR, where it is licensed by ALK to Torii and marketed under the trade name MITICURE™ and in Australia for HDM AR and AA, where it is licensed by ALK to Seqirus. The product is also being developed for a number of other markets around the world, including China, North America and countries in Southeast Asia. Altogether, clinical development

activities for the HDM SLIT-tablet have involved more than 6,000 patients worldwide.

In the 12 European countries where ACARIZAX® has been approved for HDM AR and AA, ACARIZAX®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:

- *Persistent moderate to severe HDM allergic rhinitis despite the use of symptom-relieving medication*
- *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 before initiation of treatment*

Asthma relevant contraindications:

- *Patients with FEV1 <70% of predicted value at initiation of treatment*
- *Patients who have experienced a severe asthma exacerbation within the last 3 months*
- *Patients with asthma who are currently experiencing an acute respiratory tract infection*

Treating physicians should refer to full summary of product characteristics before considering ACARIZAX® for treatment in patients with house dust mite allergic asthma.[3)]

About GINA[4)]
GINA was launched in 1993 in collaboration with the National Heart, Lung, and Blood Institute, National Institutes of Health, USA, and the World Health Organization. GINA's programme is determined and its strategies for asthma care are shaped by committees made up of leading asthma experts from around the world.

The GINA Scientific Committee prepares updates to their reports and guidelines each year, which are made available on the GINA Website as they are completed. The Scientific Committee has developed a sophisticated set of procedures to review the world's literature with regards to asthma management and to update the GINA documents to reflect this state-of-the-art information.

References:

1. *GINA, Global Strategy for Asthma Management and Prevention (2017 update), http://ginasthma.org/*
2. *Virchow JC, Backer V, Kuna P, et al. JAMA 2016;315(16):1715-25. doi: 10.1001/jama.2016.3964*
3. *ACARIZAX® 12 SQ-HDM oral lyophilsate Summary of Product Characteristics. ALK Abello A/S, August 2015*
4. *http://ginasthma.org/*