Fase III data fra astmastudie med ALKs husstøvmidetablet ACARIZAX® publiceret i førende amerikansk tidsskrift

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that The Journal of the American Medical Association (JAMA) has published results from a Phase III clinical trial evaluating the treatment of house dust mite (HDM) allergic asthma with the company's HDM sublingual allergy immunotherapy tablet (SLIT-tablet) ACARIZAX®. The results appear in the latest edition of JAMA.

Professor J. Christian Virchow, University of Rostock, lead author of the publication said: *"JAMA is one of the world's most prestigious and influential medical journals and its decision to publish these key results from the ACARIZAX® clinical development programme illustrates the ground-breaking nature of this new treatment."*

Henrik Jacobi, ALK's Executive Vice President of Research and Development, said: *"With its approval in Europe last year, ACARIZAX ® became the first and only HDM SLIT-tablet to be indicated for both allergic rhinitis and allergic asthma, and can even be used in patients with not well controlled house dust mite allergic asthma. ACARIZAX® works by addressing the cause of house dust mite respiratory allergic disease and provides an underlying protection and disease control. The published results strengthen the case for using ACARIZAX® to treat house dust mite allergic asthma".*

Trial design
The randomised, double-blind, placebo-controlled trial took place between August 2011 and April 2013 and involved 834 adult patients with HDM allergic asthma and HDM allergic rhinitis, which were not well-controlled by inhaled corticosteroids (ICS). The trial was conducted at 109 sites in 13 European countries and forms part of ALK's ongoing clinical development programme for ACARIZAX ®, which has recently been approved in 11 European countries and where it is currently being launched.

Patients were treated daily with either a 12 SQ-HDM or a 6 SQ-HDM dose, or with placebo in addition to ICS and short-acting beta-agonists (SABA). After a period of treatment varying between seven and 12 months, daily ICS use was reduced by half for three months and subsequently withdrawn completely for another three months for patients who did not experience an asthma exacerbation.

The primary endpoint of the trial was reduction in the risk of moderate to severe asthma exacerbations during steroid reduction as measured by the time to the first exacerbation.

Secondary analysis looked at patients' daytime symptoms, nocturnal awakenings, their use of SABA – typically used as asthma 'rescue' medication – and the time to their first severe asthma exacerbation both prior to and during ICS reduction.

Primary endpoint met
The trial showed that 12 SQ-HDM (the dose approved in the EU) significantly reduced the risk of a moderate or severe asthma exacerbation relative to placebo with a hazard ratio (HR) of 0.66, corresponding to a 34% risk reduction. This included:

- A 36% reduction in risk of nocturnal awakening or increase in daily symptoms (HR: 0.64)
- A 48% reduction in the risk of increased use of SABA treatments (HR: 0.52)
- A 42% reduction in the deterioration of lung function (HR: 0.58)

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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 1,900 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 Seqirus to commercialise sublingual allergy immunotherapy tablets in North America, 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.

In Europe, 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.*

About the global HDM development programme
An HDM SLIT-tablet is also being developed for a number of other markets around the world in collaboration with ALK's partners – by MSD (known as Merck in the USA and Canada) for North America, Abbott for Russia and South-East Asia, Seqirus for Australia and New Zealand, and Torii for Japan. Together, these development activities have involved more than 6,000 patients worldwide and the clinical programme makes the product the best documented in the history of HDM allergy immunotherapy. The HDM SLIT-tablet has already been launched by Torii in Japan under the brand name MITICURE^{TM}.

About the Journal of the American Medical Association (JAMA)
JAMA, published continuously since 1883, is an international peer-reviewed general medical journal with the key objective of promoting the science and art of medicine, and the betterment of the public health. It is the most widely circulated medical journal in the world, with more than 320,000 recipients of the print journal, 1.2 million recipients of electronic tables of contents and alerts, and nearly 15 million annual visits to the journal's website. JAMA's reach includes a growing social media presence (108,000 Twitter and 157,000 Facebook followers) and vast international news media exposure, including more than 20 million viewers of the JAMA video news report each week. JAMA's acceptance rate is 9.5% of the more than 7,100 major manuscripts it receives annually and just 4% of the more than 4,800 research papers received.