

Press release

Hørsholm
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ALK's partner, MSD, publishes Phase II data on house dust mite SLIT-tablet in leading allergy journal

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Results show significant improvement of nose and eye symptoms

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that its partner, MSD, known as Merck (NYSE: MRK) in the USA and Canada, has published positive results from a Phase II environmental exposure chamber trial evaluating the onset and dose-related efficacy of the house dust mite (HDM) sublingual allergy immunotherapy tablet (SLIT-tablet). The results appear in the latest printed edition of The Journal of Allergy and Clinical Immunology (JACI).

Study design

The randomised, double-blind trial took place between October 2012 and August 2013 and enrolled 124 patients with HDM allergic rhinitis with or without conjunctivitis and with or without asthma. The study was conducted at a single site in Vienna, Austria and forms part of MSD's clinical development programme for the HDM SLIT-tablet in North America.

Over the course of 24 weeks, patients were treated daily with either a 12 developmental units (DU) or 6 DU dose of the HDM SLIT-tablet, or placebo. Before the trial began, and again after eight, 16 and 24 weeks of treatment, patients were exposed to HDM allergen using the Vienna Challenge Chamber – placing them in a room containing a precisely controlled HDM allergen load for six hours to induce an allergic response – and were asked to score their allergy symptoms every 15 minutes. The primary endpoint was the total nasal symptom score (TNSS). Total ocular symptoms score and asthma symptoms were also recorded.

Positive results

By week 24, patients reported that the higher 12 DU dose HDM SLIT-tablet improved nose symptoms by 49%, and eye symptoms by 68%, compared with placebo. Nose and eye symptoms also improved with the 6 DU dose HDM tablet, but to a lesser extent.

The most commonly reported side effects were mild-to-moderate throat irritation and temporary swelling of the mouth after dosing during the first weeks.

Henrik Jacobi, Executive Vice President, Research & Development at ALK, said: "These results, together with those from nearly 2,000 patients in ALK's MERIT and MITRA trials late last year, continue to build a solid body of evidence that the house dust mite sublingual immunotherapy tablet can be an important new treatment option for treating house dust mite allergic patients whose condition is not well controlled by existing medications".

About house dust mite allergy

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. In Europe ALK estimates that up to 13% of patients with HDM 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.

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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 1,800 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.

About the Journal of Allergy and Clinical Immunology

The Journal of Allergy and Clinical Immunology publishes high-impact, cutting-edge clinical and translational research papers for allergists, immunologists, dermatologists, gastroenterologists, and other physicians and researchers interested in allergic diseases and clinical immunology. Articles cover such topics as asthma, food allergy, allergic rhinitis, atopic dermatitis, primary immune deficiencies, occupational and environmental allergy, and other allergic and immunologic diseases, and include clinical trials and mechanistic studies that report on novel therapies, insights into underlying mechanisms, and other discoveries that will inform understanding of these diseases and ultimately improve the diagnosis and management of patients. With an impact factor of 11.248, the journal ranks 1st of 23 in the Allergy category and 7th of 135 in the Immunology category in the 2013 Journal Citation Reports.