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ALK's partner in North America, Merck, presents data on investigational house dust mite sublingual allergy immunotherapy tablet

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF): ALK's partner in North America, Merck (NYSE: MRK), known as MSD outside the USA and Canada, presents new data from a Phase IIb trial with its investigational sublingual house dust mite allergy immunotherapy tablet at the annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in San Diego, USA.

The trial results showed that both doses of active treatment significantly reduced the average total nasal symptom score compared to placebo in adults with house dust mite-induced allergic rhinitis.

Merck has issued a news release concerning the findings from the clinical trial. The release is enclosed in full length on the following pages. Alternatively, it can be found on www.merck.com.

House dust mite allergy is the most prevalent allergy-induced respiratory disease in the world. The global development programme for the investigational sublingual house dust mite allergy immunotherapy tablet covers three major markets: In Europe, ALK has announced positive outcome from two pivotal Phase II/III trials and plans for regulatory filing in 2014. In Japan, Torii is expected to announce results from two pivotal Phase II/III trials in 2014. In North America, Merck plans to continue with the clinical development and initiate a Phase III trial in 2014.

This announcement does not change ALK's outlook for the financial year 2014.

ALK-Abelló A/S

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

About the partnership with Merck in North America

ALK has entered into a strategic partnership with Merck to develop, register and commercialise a portfolio of sublingual allergy immunotherapy tablets against grass pollen, ragweed and house dust mite allergy in the USA, Canada and Mexico. Under the agreement, ALK will receive up to DKK 1.6 billion (USD 290 million) in milestone payments from Merck, of which, approximately DKK 300 million has already been recognised in the years 2007-13. In addition, ALK is entitled to royalty payments on the net sales of the products on the North American market as well as payments for product supply. Merck will be responsible for all costs of clinical development, registration, marketing and sales of the products on the North American markets. ALK will be responsible for tablet production and supply.



News Release

FOR IMMEDIATE RELEASE

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Merck Announces Results from Phase 2b Study of MK-8237, an Investigational House Dust Mite Sublingual Allergen Immunotherapy Tablet

Data Presented at the 2014 Annual Meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI)

WHITEHOUSE STATION, N.J., March 4, 2014 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced results from a Phase 2b study evaluating two doses of its investigational house dust mite sublingual immunotherapy tablet (MK-8237). The data were presented for the first time during a late-breaking oral session at the 2014 Annual Meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in San Diego.

The study was conducted in 124 adult patients 18 years of age and older with house dust mite-induced allergic rhinitis, with or without conjunctivitis, using an environmental exposure chamber. In the study, MK-8237 at once-daily doses of 6 Development Units (DU) and 12 DU produced a significant dose- and time-dependent reduction in average total nasal symptom score (TNSS) over the last four hours of the chamber challenge at week 24 of treatment compared to placebo (-27%=6 DU, -49%=12 DU; $p < 0.05$ for both vs. placebo), the primary efficacy endpoint of the study. TNSS is the total score for four nasal symptoms: itchy nose, blocked nose, runny nose and sneezing.

“Merck is committed to the research and development of sublingual tablet immunotherapy options for the treatment of allergic rhinitis,” said Dr. Sean Curtis, vice president, Respiratory and Immunology, Merck Research Laboratories. “We look forward to continuing with Phase 3 research, which will provide further insight into the safety and efficacy of MK-8237.”

Study Design

In this double-blind, single-site, Phase 2b study, 124 adults, 18 years of age or older, with house dust mite-induced allergic rhinitis, with or without conjunctivitis, were randomized to receive 6 DU (n=41) or 12 DU (n=42) of MK-8237 sublingual tablets once daily for 24 weeks or placebo (n=41). Sensitivity to house dust mite allergen was determined by specific IgE testing. Patients with unstable uncontrolled/partially controlled or severe asthma were excluded from the study, as were patients with forced expiratory volume in 1 second (FEV₁) <70 percent of predicted value. Participants were exposed to the house dust mite allergen using an environmental exposure chamber at weeks 8, 16 and 24. This method allows for controlled and reproducible conditions that provide a constant concentration of allergen over a six-hour period with patients recording symptoms every 15 minutes.

Study Results

Both doses of MK-8237 showed a significant dose- and time-dependent reduction in average TNSS over the last four hours of the chamber challenge at week 24 of treatment compared to placebo (-27%=6 DU, -49%=12 DU; p<0.05 for both vs. placebo). Key secondary efficacy endpoints of the study were average TNSS over the last four hours of the chamber challenge at weeks 8 and 16 compared to placebo, and average total symptom score (TSS) over the last four hours of the chamber challenge at week 24 compared to placebo. TSS is the total score for four nasal symptoms (itchy nose, blocked nose, runny nose and sneezing) and two ocular symptoms (gritty feeling/red/itchy eyes and watery eyes). MK-8237 demonstrated dose-dependent reductions versus placebo in average TNSS at week 8 (-8%=6 DU; p=NS and -20%=12 DU; p<0.05) and at week 16 (-18%=6 DU, -30%=12 DU; p<0.05 for both vs. placebo). MK-8237 also demonstrated dose-dependent reductions versus placebo in average TSS at week 24 (-29%=6 DU, -52%=12 DU (p<0.05 for both vs. placebo).

In this study, the most common adverse events (incidence ≥ 5%) occurring in patients receiving MK-8237 6 DU, 12 DU or placebo, respectively, were throat irritation (34%, 52%, 0%), mouth edema (24%, 24%, 0%), lip swelling (5%, 17%, 2%), oral pruritus (15%, 14%, 0%), dyspepsia (2%, 10%, 0%), ear pruritus (0%, 7%, 0%), swollen tongue (0%, 5%, 0%), oropharyngeal swelling (0%, 5%, 0%) and pharyngeal edema (2%, 5%, 0%). There were no local swellings of severe intensity and no serious adverse events reported in patients treated with MK-8237. The majority of adverse events in this study were assessed as mild or moderate. There were no investigator reported systemic allergic reactions or reactions treated with epinephrine for either dose of MK-8237.

A Phase 3 study of MK-8237 in adolescents and adults with house dust mite-induced allergic rhinitis is currently screening patients. Details of the study can be viewed on [ClinicalTrials.gov](https://clinicaltrials.gov).

Additional Merck Research Presented at AAAAI

- Efficacy of the Short-Ragweed Sublingual Immunotherapy Tablet MK-3641 in Monosensitized and Polysensitized Subjects (Poster 756);
- The Effect of the Ragweed Sublingual Immunotherapy Tablet MK-3641 on Rescue Medication Use (Poster 972);
- The Efficacy and Safety of the Short-Ragweed Sublingual Immunotherapy Tablet MK-3641 is Similar in Asthmatic and Nonasthmatic Subjects Treated for Allergic Rhinitis with/without Conjunctivitis (AR/C) (Poster 754);
- Magnitude of Changes in Patient Symptom and Medication Scores in Grass Allergy Immunotherapy Trials: Dependency on Levels of Pollen Exposure (Poster 767).

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](https://twitter.com/merck), [Facebook](https://facebook.com/merck) and [YouTube](https://youtube.com/merck).

Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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