

Selskabsmeddelelse nr. 9/2014

Hørsholm
4. marts 2014

ALKs partner i Nordamerika, Merck, præsenterer resultater med tabletvaccinen mod husstøvmideallergi

Side 1/6

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF): ALKs samarbejdspartner i Nordamerika, Merck (NYSE: MRK), kendt som MSD uden for USA og Canada, præsenterer nye data fra et klinisk fase IIb-studie med tabletvaccinen mod husstøvmideallergi på årsmødet i American Academy of Allergy, Asthma & Immunology (AAAAI) i San Diego, USA.

Resultaterne fra studiet viste, at begge doser af den aktive behandling reducerede den gennemsnitlige totale score for næsesymptomer signifikant sammenlignet med placebo i voksne med allergisk rhinitis forårsaget af husstøvmider.

Merck har offentliggjort en pressemeddelelse om resultaterne fra det kliniske studie. Pressemeddelelsen findes i sin fulde længde på de efterfølgende sider. Meddelelsen kan også findes på www.merck.com.

Husstøvmideallergi er den mest udbredte allergiske luftvejslidelse i verden. Det globale udviklingsprogram for tableten mod luftvejslidelser forårsaget af husstøvmider dækker tre vigtige markeder: I Europa har ALK offentliggjort positive resultater fra to pivotale fase II/III-studier og planlægger indsendelse af en registreringsansøgning om godkendelse i 2014. I Japan forventes Torii at offentliggøre resultater fra to pivotale fase II/III-studier i 2014. I Nordamerika forventer Merck at fortsætte det kliniske udviklingsprogram og igangsætte et fase III studie i 2014.

Denne meddelelse ændrer ikke ALKs forventninger til regnskabsåret 2014.

ALK-Abelló A/S

For yderligere oplysninger kontakt venligst:

Jens Bager, adm. direktør, tlf. 4574 7576

Investor Relations: Per Plotnikof, tlf. 4574 7527, mobil 2261 2525

Presse: Martin Barlebo, tlf. 4574 7901, mobil 2064 1143

Om ALK

ALK er en global, forskningsbaseret medicinalvirksomhed, der fokuserer på forebyggelse, diagnosticering og behandling af allergi. ALK er verdens førende virksomhed inden for allergivaccination (immunterapi) – en unik behandling af selve årsagen til allergi. Virksomheden har ca. 1.800 medarbejdere og datterselskaber, produktionsfaciliteter og distributører over hele verden. ALK har indgået partnerskabsaftaler med Merck og Torii om kommercialisering af sublinguale tabletbaserede allergivacciner i henholdsvis Nordamerika og Japan. Selskabet har hovedkvarter i Hørsholm og er børsnoteret på NASDAQ OMX Copenhagen A/S. Læs mere på www.alk.net.

Om samarbejdet med Merck i Nordamerika

ALK har indgået et strategisk partnerskab med Merck om at udvikle, registrere og kommercialisere en portefølje af sublinguale tabletbaserede allergivacciner mod græs-, ragweed- og husstøvmideallergi i USA, Canada og Mexico. I henhold til aftalen er ALK berettiget til at modtage op til DKK 1,6 mia. (USD 290 mio.) i milepælsbetalinger fra Merck, hvoraf ca. DKK 300 mio. allerede er indtægtsført i årene 2007-13. ALK vil derudover modtage royaltybetalinger fra nettosalget af produkterne på det nordamerikanske marked samt betalinger for produktleverancer. Merck afholder alle omkostninger til klinisk udvikling, registrering, markedsføring og salg af produkterne på det nordamerikanske marked. ALK er ansvarlig for produktion og levering af tabletterne.



News Release

FOR IMMEDIATE RELEASE

Media Contacts: Pam Eisele
(267) 305-3558

Robert Consalvo
(908) 423-6595

Investor Contacts: Carol Ferguson
(908) 423-4465

Justin Holko
(908) 423-5088

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).

#