

New data shows ALK's house dust mite SLIT-tablet significantly improves quality of sleep for allergic rhinitis patients

- Approximately 9 out of 10 trial subjects with 'moderately or severely affected sleep' saw an improvement following treatment with ALK's HDM SLIT-tablet.
- The results were revealed by a post-hoc analysis of sleep-specific data from the MERIT Phase III clinical trial of ALK's house dust mite SLIT-tablet
- The findings were presented for the first time at this year's Annual Meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI)

ALK has released new analysis of clinical trial data showing that its sublingual allergy immunotherapy (SLIT) tablet for the treatment of house dust mite (HDM)-related allergy can significantly improve quality of sleep for allergic rhinitis patients.

The results were presented for the first time on Monday, 25 February 2019 as a scientific poster at the Annual Meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI) in San Francisco, California, and were gathered during a post-hoc analysis of data from the MERIT Phase III clinical trial to evaluate the efficacy and safety of the HDM SLIT-tablet in the treatment of allergic rhinitis.

Sleep issues are common in patients with uncontrolled allergic rhinitis, with one study reporting that 24% have difficulty falling asleep, 26% lack a good night's sleep, and 31% have difficulty staying asleep.ⁱ Another study reported that almost 74% of adults with HDM-induced allergic rhinitis had consulted a doctor about the impact of their allergy on their sleep and concluded that sleep disorders were high in frequency and significant in their impact.ⁱⁱ

ALK's HDM SLIT-tablet has previously been shown to be effective in treating HDM-induced allergic rhinitis and/or conjunctivitis as well as HDM-induced allergic asthma. This new analysis of the MERIT trial data was conducted using data from a Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), which participants completed at the outset of the MERIT trial and throughout the treatment period. Sleep issues were tracked via scores ranging from 0 (not troubled) to 6 (extremely troubled), rating three common consequences of HDM allergy symptoms: lack of a good night's sleep, waking during the night, and difficulty getting to sleep.

Analysis showed that, at the beginning of the trial, approximately 65% of participants had moderately or severely affected sleep. Of those, the majority saw an improvement following treatment with the HDM SLIT-tablet with only 7.3-10.1% remaining in the moderate/severe category at the end of trial. This improvement was significantly better than that observed following treatment with placebo. In addition, the RQLQ adjusted mean score for the sleep scores was significantly better among the HDM SLIT-tablet group than for the placebo group.

ALK's Executive Vice President of Research and Development, Henrik Jacobi, said: "We know from discussions with doctors and patients alike that sleep disorders have a major impact on quality of life for people living with respiratory allergies. The consequences of a poor night's sleep can carry over into the next day, affecting attention-span, concentration, as well as the ability to learn or to retain information. This analysis shows that, for the appropriate patients, treatment with ALK's house dust mite SLIT-tablet could make a significant difference."

The MERIT trial was a double-blind, placebo-controlled, multi-centre Phase III trial initiated by ALK in 2011, and involved 992 adults who had moderate-to-severe HDM-induced allergic rhinitis, despite receiving symptomatic treatment. Participants received either placebo, 6 SQ-HDM, or 12 SQ-HDM tablets, once a year for up to one year. For this post-hoc analysis, results from the 12 SQ-HDM group and the placebo group were used, as 12 SQ-HDM is the dose that was subsequently approved by the US Food and Drug Administration in the Biologics License Application for the HDM SLIT-tablet.

In 2015, ALK's HDM SLIT-tablet was approved in Europe for use in HDM-induced allergic rhinitis and allergic asthma, and in Japan for allergic rhinitis. A US approval followed in 2017 for use in allergic rhinitis. The product is marketed as ODACTRA™ in the USA, MITICURE™ in Japan, and ACARIZAX® in other markets around the world. Specific indications and labelling restrictions vary according to market.

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About ALK

ALK is a global allergy solutions company, with a wide range of allergy treatments, products and services that meet the unique needs of allergy sufferers, their families and doctors. Headquartered in Hørsholm, Denmark, the company employs around 2,300 people worldwide and is listed on Nasdaq Copenhagen. To learn more about ALK and allergies, visit www.alk.net.

ⁱ Ref: Meltzer et al. J Fam Pract. 2012;61(2 Suppl);S5-10

ⁱⁱ Ref: Leger et al. Allergy Asthma Clin Immunol. 2017 Aug 16;13:36