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Clinical relevance of the SQ HDM SLIT-tablet in adolescents with moderate-to-severe house dust mite allergic rhinitis
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Introduction
House dust mite (HDM) respiratory allergy is a common and burdensome disease in children and adolescents. The SQ HDM sublingual immunotherapy (SLIT) tablet has shown to be efficacious in adults and adolescents with HDM allergic rhinitis. This abstract presents findings illustrating the clinical relevance of the efficacy from pooled data from adolescents (12-17 years) included in 2 phase III trials.

Methods
In 2 DBPC trials conducted in North America (clinicaltrials.gov identifier NCT01700192) and Japan (JapicCTI number 121848), subjects aged 12+ years with moderate-to-severe HDM allergic rhinitis were randomised to up to one year of treatment. The primary endpoint was the average total combined rhinitis score (TCRS) during the last 8 weeks of treatment in the active group compared to placebo. Data from subjects aged 12–17 years were pooled. Post-hoc analyses concerning rhinitis exacerbation days and mild days were done for placebo versus 12 SQ-HDM. A rhinitis exacerbation day was defined as a day with an allergic rhinitis symptom score of 6, or 5 with one individual symptom scored 3 (i.e. implying a symptom that is hard to tolerate and causes interference with activities of daily living and/or sleeping). A mild day was defined as a day with no individual symptom scored higher than 1 (i.e. the symptom was clearly present but caused minimal awareness and was easily tolerated) and no antihistamine use.

Results
In the pooled adolescent subpopulation (N=395), the average TCRS improved 22% with 12 SQ-HDM versus placebo (absolute difference of 1.04;p=0.002). The estimated probability of experiencing a rhinitis exacerbation was 22.6% for placebo and 9.3% with 12 SQ-HDM (OR=0.35; 95% CI [0.14; 0.88]; p=0.026). The estimated probability for experiencing a mild rhinitis day was 28.5% with placebo and 47.1% with 12 SQ-HDM (OR=2.23; 95% CI [1.18; 4.24]; p=0.014). Extrapolated to a full year, this corresponds to 82 days with rhinitis exacerbation and 3½ months of mild days in the placebo group, compared with 34 days with rhinitis exacerbation and almost 6 months of mild days in the 12 SQ-HDM group.

Conclusion
Treatment with 12 SQ-HDM significantly improved the TCRS in adolescents with moderate-to-severe HDM allergic rhinitis. Furthermore, the treatment reduced the patient's probability for having rhinitis exacerbation days and increased the probability for having mild days with no more than minimal awareness of symptoms. Taken together these findings illustrate the clinical relevance of the SQ HDM SLIT-tablet seen in adolescents in moderate-to-severe HDM allergic rhinitis.