

corticosteroid/antibiotic combinations. Poisson regression was used to compare changes over time in rescue symptomatic medication use in the 2 groups. Confounding variables (gender, age at the index date, main prescriber, asthma status at the index date and number of AC Rx before and duration of the analysis) were corrected for in all analyses. The database does not include any safety data.

Results: After applying all selection criteria, 2,851 SLIT and 71,275 CT were selected for the study. After treatment cessation, AR medication use was 18.8 percentage points lower and a significant long-term effect in improvement on the progression of conjunctivitis compared with CT group was observed during treatment: Regression Coefficient (RC) [95% confidence interval (CI)] = 0.74 [0.49- 0.99]; $p < 0.001$ and after treatment cessation RC [95% CI] = 1.18 [0.86- 1.50]; $p < 0.001$.

Conclusion: The grass pollen sublingual tablets have a significant effect on the progression of the allergic conjunctivitis.

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TREATMENT BENEFIT OF THE 5-GRASS TABLET IN CHILDREN: ASSESSMENT FROM THE PATIENT'S POINT OF VIEW



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Introduction: SLIT with the 5-grass pollen tablet (5-G) has shown its efficacy in the treatment of allergic rhinitis (AR) in children in a randomized controlled trial. A validated instrument for the assessment of patient-relevant benefit in the treatment of AR has been developed: the Patient Benefit Index (PBI-AR). In this sub analysis we investigated the benefit of 5-G in children aged 5-12 years* as indicated in Germany.

Methods: In an open, prospective, multicenter, non-interventional study conducted in 145 German study centers, children were observed during their 1st treatment period with the 5-G using the PBI-AR. The PBIAR was computed based on the assessment of treatment needs and benefits (0=no benefit to 4=maximum benefit). A PBI-AR global score = 1 is defined as relevant benefit.

Results: 246 children were included in this analysis, for 163 of whom a PBI-AR global score could be computed. Children achieved a mean PBI of 2.61 ± 0.99 . Of the 4 PBI-AR dimensions the first showed the highest benefit for the children (2.82 ± 1.14). In total, 94.6% of the patients achieved relevant benefit from treatment with the 5-G (PBI=1). The PBI-AR global score was significantly associated with the physicians' assessment of improvement. The children's impairment by AR symptoms decreased during the treatment. The PBI-AR global score significantly correlated with a change in the impairment by AR symptoms ($r = -0.438$, $p < 0.001$). Having no side effects was one treatment goal in 20.6% of patients.

Conclusion: In the first year of treatment, the 5-grass pollen tablet already attained children patient-relevant benefit.

*The US indication is for patients 10-65.

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HOUSE DUST MITE SUBLINGUAL TABLETS: SUBJECT PROFILE AND EXPOSURE IN CLINICAL DEVELOPMENT PROGRAM



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Introduction: The clinical program of house dust mite (HDM) tablets* is conducted for treatment of patients with HDM-associated allergic rhinitis (HDM-AR). Here we present the clinical profile of enrolled adults, adolescents and children.

Methods: 9 DBPC trials (8 completed, 1 ongoing) investigated efficacy and/or safety of HDM tablets (100IR to 1,500IR doses)

worldwide. Enrolled subjects (5–64 years) had HDM-AR for ≥ 1 or 2 years confirmed by positive skin prick test (nasal provocation test in Japan) and HDM-specific IgE, and sufficient symptom level (score $\geq 5/12$ or $\geq 6/15$). Those receiving GINA treatment Step 1 for asthma and those co-sensitized to allergen(s) other than HDM without clinically relevant symptoms during the trial could participate. Subject baseline characteristics from 7 trials completed before 2016 were pooled and analyzed descriptively.

Results: Data from 1,571 subjects (1,182 adults, 261 adolescents, 128 children) receiving ≥ 1 dose of HDM tablets and 836 placebo-recipients (536 adults, 182 adolescents, 118 children) were analyzed. Subjects (mean age 26 years) were mainly Caucasian or Asian. 60% were poly-sensitized, 26% had asthma. 70% were actively treated for ≥ 6 months (maximum: 411 days). In the recently completed trial (Japan), 438 subjects (5–16 years) were treated with either placebo or 300IR for 12 months. In an ongoing trial, up to 1,700 subjects (12–65 years) will receive either placebo or 300IR for 12 months.

Conclusions: Overall, >2,500 subjects will be exposed to HDM tablets with ~1,900 receiving 300IR for up to 13.5 months, thus confirming evidence of the efficacy and safety for HDM-AR.

*This product is not approved in the US.

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HARBINGER OF A NEW ERA IN ALLERGY TREATMENT

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Introduction: Antigens presented on the surface of an organized structure cause a strong immunogenic response. We have developed allergen-bearing bio-particles and are currently investigating their overall efficacy to induce immune tolerance.

Methods: A proprietary plant-based system was developed to produce by transient expression allergen-bearing bio-particles, the chosen allergen being represented in a geometrically repetitive pattern known to induce a TH-1 biased immune response. External validation ascertained the quality of the allergenic proteins produced, while a murine model sought to clarify 1- the allergenicity of soluble allergenic proteins produced and 2- the hypoallergenic nature of bio-particles carrying the same allergens. Basophil activation testing (BAT) finally was called to validate the same notion in vitro.

Results: Among the advantages of our allergen-bearing bio-particles is their quick, simple and inexpensive production. These bio-particles contain thousands repeats of a chosen allergen molecule on their surface. In contrast with an allergen presented in the form of a soluble monomer, our results indicate that the same allergen presented on the surface of these organized structures causes a strong immunogenic response, and this without inducing allergic reaction in mice nor degranulation in BAT.

Conclusion: Combining a new, competitive manufacturing technology with a new 3D allergen display of allergenic proteins, we present innovative biotechnology that aims to bring to clinicians in vivo molecular allergy testing and to push the envelope of allergy therapeutic expectations beyond the realm of current immunotherapy.

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AN UNUSUAL CASE OF DELAYED PRESSURE URTICARIA AFTER RUSH IMMUNOTHERAPY

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Introduction: Rush immunotherapy (RIT) is a valid alternative to reach maintenance phase early. Therapeutic maintenance doses are