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Title: Efficacy and safety of 300IR 5-grass pollen sublingual tablet in allergic patients with and without asthma

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Body: Background Efficacy and safety of 300IR tablet has been demonstrated. Here we report the impact of asthma status on efficacy and safety. Methods Grass pollen allergic adults were randomised to placebo or 300IR pre- and co-seasonally for 3 seasons, starting 4 months (4M) or 2 months (2M) prior to each season and continuing for its duration. Asthmatic patients requiring no more than GINA Step 1 therapy could be included. The primary efficacy endpoint, Average Adjusted Symptom Score (AAdSS, adjusting rhinoconjunctivitis symptoms for rescue medication use, scale 0-18) during the pollen period in Year 3, was analysed by ANCOVA. Asthma presence at baseline was a pre-specified covariate. Treatment by asthma status interaction was tested. Results Among 581 patients included in the Year 1 full analysis set, 14.1% were asthmatic, with balance between groups. In Year 3, differences in AAdSS Least-Squares means vs. placebo during the pollen period were significant in the two active groups ($p<0.0001$) corresponding to a relative difference of -34.9% in the 4M group and -37.6% in the 2M group. Asthma status was not a significant predictor of outcome. Interaction between treatment and asthma status was not significant ($p=0.62$) indicating that treatment effect was independent of asthma status. No significant difference was observed between the 4M and 2M groups. During the 3 treatment years, 3 patients had an asthma exacerbation (moderate): 2 in Year 1 (placebo) and one in Year 3 (4M). None was drug-related. Conclusion Efficacy and tolerability of 300IR 5-grass pollen sublingual tablet in patients with grass pollen allergic rhinoconjunctivitis were similar in those with and without asthma.