

## #1500 - Efficacy of a 3-week subcutaneous immunotherapy course in patients with grass pollen-induced rhinoconjunctivitis: Results of a phase-3 study

Mösges, Ralph / Panzner, Petr / Pfaar, Olivier / Thomson, Marc / Haazen, Ludo / Bonny, Marie-Alix / Von Frenckell, Rémy / Piroton, Sabine / Legon, Thierry / Durham, Stephen R / Shamji, Mohamed H / Bachert, Claus

### Introduction

Subcutaneous allergen immunotherapy (AIT) is safe and efficacious for the treatment of grass pollen rhinoconjunctivitis. Two major issues with current immunotherapy are the long-term treatment schedule and poor adherence. A novel AIT using *Lolium perenne* peptides (LPP), based on highly purified allergen fragments from natural sources, has been developed for a 3-week treatment course for grass pollen rhinoconjunctivitis. This study investigated the clinical efficacy, tolerability, and safety of LPP during natural exposure to grass pollen.

### Objectives

This phase-III, double-blind, placebo-controlled study randomised 554 patients with grass pollen-induced rhinoconjunctivitis with or without controlled asthma (ratio 1:2) to receive once-weekly injections of placebo or increasing doses of LPP, reaching the cumulative dose of 170 µg in 3 weeks. The primary endpoint was the average combined score (CSMS) of the daily total rhinoconjunctivitis symptom score (RTSS) and the daily medication score (RMS) during the peak of the subsequent grass pollen season. The reduction in reactivity to the conjunctival provocation test (CPT) was assessed as the secondary efficacy endpoint. Tolerability was assessed by monitoring local reactions, while safety assessments included systemic allergic reactions and treatment emergent adverse events.

### Results

After treatment with LPP, the CSMS improved significantly by 15.5% ( $P=0.041$ ) and RTSS by 18.5% ( $P=0.013$ ) during the pollen peak compared with placebo (Mann-Whitney test, intention-to-treat population: 171 patients in placebo and 339 patients in LPP groups). In addition, a 46% reduction in lung symptoms was observed in asthmatic patients treated with LPP compared to placebo. Reactivity to CPT decreased significantly in 60.0% of LPP-treated patients compared with 35.6% in the placebo group ( $P<0.0001$ , Chi-square test). 89.4% of the patients reached the cumulative dose of 170 µg as defined in the protocol. 5.4% of patients under LPP discontinued treatment due to generally mild local or systemic reactions. No relationship was observed between the frequency/severity of adverse events and the injected dose.

### Conclusions

This study's data demonstrate that 3-week treatment with increasing doses of LPP (gpASIT+) confers clinical benefits to grass pollen-allergic patients during natural exposure to allergens. These results also confirm the overall good tolerability and safety of this novel immunotherapy approach.