Sustained Efficacy of AllerT Allergy Vaccine After A Second Birch Pollen Season: A Phase IIb

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Rationale: AllerT™ (Anergis SA, Switzerland), based on three contiguous overlapping peptides (COPs) derived from Betv1, was successfully administered according to an 2-month immunotherapy regimen to patients with birch pollen allergic rhinoconjunctivitis in a placebo-controlled, double-blind, randomized, multicenter, phase IIb study (AN004T, 2013), and reached efficacy and safety endpoints. The aim of the current study (AN005T) was to assess the efficacy of AllerT™ during a second follow up seasonal exposure without additional treatment.

Methods: 196 patients out of the 239 patients from AN004T study, including 3 arms (placebo, 50μg and 100μg COPs in Aluminum Hydroxide), were enrolled into the follow up study AN005T during the 2014 birch pollen season. Efficacy was evaluated using the combined Rhinoconjunctivitis Symptom and Medication Score (RSMS) as primary endpoint as well as quality of life assessment and other secondary endpoints.

Results: According to per protocol analysis, LS Mean RSMS was improved by 21% with AllerT 50μg and 18% with AllerT 100μg (Wilcoxon: p=0.02 and p=0.07, respectively). Both AllerT 50μg and 100μg doses were associated with similar improvements in quality of life (Mini-RQLQ: 21% and 20%; p=0.03 and p=0.05, respectively). Night-time Nasal Symptom Score (NNSS) was improved by 30 and 39% (p=0.014 and p=0.003, respectively).

Conclusions: AllerT™ was previously found to be safe, well tolerated and efficacious during the first birch pollen season. This follow up study during a second seasonal exposure shows sustained efficacy in improving RSMS, Mini-RQLQ and NNSS, supporting a long term effect of an ultra-fast immunotherapy formulation based on a mixture of COPs derived from Betv1.
Persistence of elevated anti-Bet v 1 IgG4 prior and during the second pollen season after AllerT ultra-fast immunotherapy; results from a phase IIb study follow up

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Rationale: AllerT™, a mix of three Contiguous Overlapping Peptides (COPs) derived from the major birch pollen allergen Bet v 1, was administered to allergic volunteers in a phase IIb study. Subjects received 5 subcutaneous injections within 2 months and showed an improvement in rhinoconjunctivitis symptoms and medication scores during the first and second birch pollen season. The present study shows the levels of allergen specific immunoglobulins in patients followed through the second pollen season without treatment.

Methods: Blood was collected before, at peak and after the 2014 birch pollen season. Anti-Bet v 1 IgG4 and IgE were quantified by ELISA.

Results: AllerT administration had been previously shown to significantly increase Bet v 1 specific IgG4 by about 20 fold compared to placebo. After about one year without treatment anti-Bet v 1 levels remained significantly elevated compared to placebo. The levels eventually further rose during the pollen season reaching about 4 fold their original levels. No difference was observed in anti-Bet v 1 IgE levels between placebo and treated groups.

Conclusions: Immunotherapy with AllerT, shown to be efficacious in both first and second pollen seasons, induces a persistent elevated anti-Bet v 1 IgG4 response even one year after administration. No major changes in anti-Bet v 1 IgE levels were observed in the treated groups except for a slight seasonal increase also observed in the placebo group. Persistent IgG4 response indicates a potential long term effect of AllerT treatment, coherent with previous phase I/IIa immunological results.