



## **Anergis Reports Encouraging Seasonal Clinical Results with AllerT, a Novel Product for Ultra Fast Desensitization of Patients Allergic to Birch Pollen**

**LAUSANNE, Switzerland – July 17, 2009 – Anergis SA, a clinical-stage biopharmaceutical company developing innovative specific immunotherapy against allergies, today announced encouraging new clinical results collected during the birch pollen season following the proof-of-concept Phase I/IIA study AN003 with subcutaneous AllerT, a novel product, based on the Contiguous Overlapping Peptides (COP) technology, for ultra fast desensitization of patients allergic to birch pollen.**

All subjects who participated in Study AN003 were asked to complete weekly validated rhino-conjunctivitis quality-of-life questionnaires (“Mini-RQLQ”, Juniper et al. 2000) during the four weeks of April 2009.

Pre-seasonal treatments with 5 injections of AllerT SC or placebo over 2 months had been completed in all patients between 2-4 months before the season and no further injection was given before or during the season. The analysis compares the results by treatment group of the “Mini-RQLQ Total Score” and of the “Rhino-Conjunctivitis Symptom Score” - a subset of the Mini-RQLQ Total Score including the items related to the specific nose and eyes symptoms of allergic rhino-conjunctivitis. These evaluations were made at each week of data collection. The investigator added with the Mini-RQLQ a specific additional question on the presence and severity of asthma episodes during the season (the “Asthma Score”), which was analyzed in the same way as the Mini-RQLQ scores.

Results: Birch pollen counts measured by the Lausanne Station in 2009 were very high during a relatively short period of 8 to 10 days, which was fully covered by the questionnaires. The peak of allergic symptoms in the placebo patients occurred at week 3 of data collection.

We observed a pronounced trend in favour of AllerT treated subjects. The Mini-RQLQ Total Score and the Rhino-Conjunctivitis Symptom Score at the peak of the season were 31 and 35% lower in AllerT treated patients than in the placebo group, respectively. The Asthma Score followed a similar pattern, with a mean score in AllerT treated patients 65% lower than in placebo treated patients.

“These results are truly remarkable since it is generally accepted that a difference of 20% or more in symptom scores (specific immunotherapy vs placebo) is considered clinically meaningful in trials of specific immunotherapy. Study AN003 has provided us with a set of very consistent results, namely key antibodies production (IgG4), key cytokine production (IL-10) and now a trend for reduced symptom scores, all pointing towards the achievement of clinical tolerance to natural birch pollen, after an ultra-fast protocol of only five injections over 2 months” commented Christophe Reymond, Ph.D., CSO of Anergis.

Professor François Spertini, M.D., principal investigator of the trial commented “After having demonstrated the feasibility of administering safely high doses of AllerT and the immunogenicity consistent with the development of allergen tolerance, we now report the most important results, an improvement of the patients’ symptoms and quality of life in the natural conditions of the pollen season. We realize that these clinical results are based on a small number of patients, but they are in full concordance with immunogenicity data. We will need confirmation but we are very excited with the prospect of being in the conditions to offer soon to our patients a quick and safe allergen specific immunotherapy”.



“With these new results, Anergis is fully focused on securing funding to progress to the next clinical study with AllerT, which will be specifically designed to demonstrate the clinical efficacy of AllerT in few hundreds of birch pollen allergic patients” concluded Vincent Charlon, PhD, CEO of Anergis, adding “We also want now to accelerate the development of new products targeted against other allergies as soon as possible”.

About AllerT: AllerT is a proprietary product of Anergis SA, currently in clinical development for the specific immunotherapy of patients with moderate to severe allergies to birch pollen. Birch pollen allergies are common in the northern hemisphere, affecting 90% of patients allergic to tree pollens. AllerT is composed of a set of peptides derived from the major birch pollen allergen Bet v 1. These peptides together contain *all* T cell epitopes of Bet v 1 but have been designed by Anergis (COP technology) to present no cross-reactivity with Bet v 1 specific IgEs. AllerT has been tested *in vitro*, in animals and in an earlier clinical trial, all showing markedly reduced or absence of IgE-mediated immediate allergic responses.

About Anergis SA: Anergis SA is a Swiss-based biopharmaceutical company specializing in the discovery and development of novel ultra-fast specific immunotherapy (also known as “SIT” or “desensitization”) products. Allergy is the most prevalent and the fastest growing chronic condition in the industrialized world with over 300 million people affected. Current SIT remains underused due to its long duration (3-5 years of treatment) and safety risks. Anergis’ objective is to provide ultra-fast SIT treatments to allergic patients, by developing safer products which can be administered safely at high doses. Anergis possesses a unique know-how and an exclusive license to the technology of Contiguous Overlapping Peptides (“COPs”) developed jointly by the University of Lausanne, Switzerland (UNIL), the Federal Institute of Technology (EPFL) and the Centre Hospitalier Universitaire Vaudois (CHUV) under the leadership of Prof François Spertini, the inventor of COPs and founder of Anergis. The technology of COPs allows the identification and development of uniquely profiled proprietary products intended for ultra-fast and safe desensitization. In the past years, Anergis has studied proprietary COPs targeting bee venom and birch pollen allergies both in animals and in humans. These studies have established the proof-of-concept of Anergis unique approach to SIT.

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