



## **Anergis SA Announces Successful Results of a Phase I/IIA Clinical Trial with Subcutaneous AllerT, its Novel Product for Desensitization of Patients Allergic to Birch Pollen**

**LAUSANNE, Switzerland – April 22, 2009 – Anergis SA, a clinical-stage biopharmaceutical company developing innovative specific immunotherapy against allergies, today announced successful results of the proof-of-concept Phase I/IIA study AN003 with AllerT, its novel product, based on the Contiguous Overlapping Peptides (COP) technology, for desensitization of patients allergic to birch pollen.**

“This new double-blind, randomized, placebo-controlled study with AllerT provides very encouraging results, which are fully consistent with our earlier experience with a COP product against bee venom allergies. In this new study involving twenty patients (placebo N=5 and AllerT N=15), safety was the primary endpoint: AllerT was well tolerated and safe in patients allergic to birch pollen and no patient experienced immediate allergic reactions, even though we administered doses equivalent to approximately ten times the maximal dose injected during conventional desensitization protocols” said Christophe Reymond, Ph.D., CSO of Anergis. “Importantly, with our secondary endpoints, we could also show marked and unequivocal immunological responses in patients treated with AllerT which are consistent with the induction of tolerance against birch pollen” added Dr Reymond.

“The results of this new study with AllerT provide further evidence supporting the concept of developing Contiguous Overlapping Peptides for the specific immunotherapy of patients with allergies,” said Vincent Charlon, Ph.D., CEO of Anergis, “COPs are safe, well-tolerated and immunogenic. We want now to progress AllerT to the next development step, namely to conduct a large-scale Phase II clinical trial with adequate statistical power to demonstrate clinical efficacy, i.e. desensitization of patients allergic to birch pollen”

Professor François Spertini, M.D., principal investigator of the trial commented “Every year we see numerous patients suffering from birch pollen allergies. We recommend specific immunotherapy to only very few of them because these treatments, whether given subcutaneously or via the sublingual route, require a 3 to 5 years commitment of the patient and are not devoid of risks of serious anaphylactic reactions. With AllerT, we can administer high doses of the allergen safely within a very short period, we have shown marked immunological responses in these patients, and we hope to show soon the induction of clinical tolerance in further seasonal studies. A fast and safe desensitization option would certainly be highly attractive to many of our patients.”

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 Study AN003: Study AN003 was the first clinical trial with repeated administrations of AllerT to patients allergic to birch pollen. This was a double-blind, randomized, placebo-controlled, single-centre study conducted at the Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland by François Spertini, M.D. Volunteers were screened for their reactivity to birch pollen and randomized to receive either AllerT or placebo. The study was designed to include two consecutive cohorts of 20 patients each: subcutaneous injections cohort (AllerT N=15, placebo N=5) and intra-dermal injections cohort (AllerT N=15, placebo N=5). The second cohort treated with intra-dermal injections is still ongoing and



has not yet been analyzed. The primary objectives of the study were to evaluate the safety and tolerability of AllerT, administered on days 1, 7, 14, 21 and 51 of the study. Adverse events were collected as solicited and non-solicited events for 4 days after each injection and collected throughout the study up to one month after the last injection. Blood was collected for analysis of immunological markers (Bet v 1 specific IgG4, Bet v 1 specific IgE, *in vitro* T cell proliferation, T cell cytokine profile) prior to the injection on days 7, 14, 21, 51 and 85. Nasal provocation tests with birch pollen were performed using stepwise pollen dose increase at screening and on day 85 of the study. These latter tests were inconclusive due to the very limited number of patients. All patients completed the study: no subject was either withdrawn from the trial prematurely or lost to follow-up. This clinical study is supported by a CTI grant from the Swiss OFFT (Office Federal de la formation et de la technologie).

François Spertini, M.D. is Associate Professor at the University of Lausanne, Division of Immunology and Allergy, Switzerland. Prof Spertini is the inventor of the technology of Contiguous Overlapping Peptides and the founder of Anergis SA to whom all rights to the technology have been transferred in 2005.

About Anergis SA: Anergis SA is a Swiss-based biopharmaceutical company specializing in the discovery and development of novel 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 make SIT treatments available to many more allergic patients than today, by providing novel safe and fast desensitization products. 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). 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 already identified and studied proprietary COPs targeting bee venom and birch pollen allergies, both in animals and in humans. These studies have clearly established the safety, tolerability and immunogenicity of the COP technology.

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