

Anergis Initiates Development of Second-Generation COP Allergy Vaccines; Announces Publication of Sustained Efficacy Data from Ph. IIb Study Follow-up

- 2-month treatment with AllerT COP allergy vaccine provides sustained clinical benefit for more than one pollen season
- Research program to develop next-generation COP allergy vaccines in progress

EPALINGES, Switzerland, September 5th, 2018 – Anergis, a company developing proprietary ultra-fast Allergy Immunotherapy (AIT), announced today that the Company has initiated the development of the second generation of its ultra-fast COP allergy vaccines. Moreover, the Company reported the publication of key proofof-concept data from a clinical phase IIb follow-up trial demonstrating sustained clinical efficacy of its birch pollen vaccine AllerT for more than one pollen season.

In 2016, results of a Phase IIb trial with the AllerT COP allergy vaccine published in the *Journal of Allergy and Clinical Immunology* [¹] demonstrated the efficacy of AllerT during the natural birch pollen season immediately following a single 2-month treatment course. The new data published in this year's August issue of the *Journal of Allergy and Clinical Immunology* [²] demonstrate that the efficacy of AllerT persisted during the following annual pollen season a year later without repeated treatment. Results were based on a follow-up including 196 of 240 patients that originally enrolled in the study.

Improvements in scores after the second season for both primary and secondary endpoints were over 20%, the threshold usually considered to be clinically relevant. Together with earlier evidence of immunological memory lasting for at least 4 years [³], these clinical data confirm the core concept of ultra-fast AIT, i.e. eliciting a persistent benefit by administering a single treatment course with a COP allergy vaccine.

For optimized clinical efficacy and tolerability, Anergis now has initiated a new

¹ Spertini et al. JACI 2016 "Efficacy of 2 months of allergen-specific immunotherapy with Bet v 1– derived contiguous overlapping peptides in patients with allergic rhinoconjunctivitis: Results of a phase IIb study" 138;1:162-168

² Kettner et al. JACI 2018 "Benefit of Bet v 1 contiguous overlapping peptide immunotherapy persists during first follow-up season" 142;2:678-680.e7

³ Spertini et al. JACI 2014 "Safety and immunogenicity of immunotherapy with Bet v 1–derived contiguous overlapping peptides" 134;1:239-240.e13



preclinical research program to design the next generation of COP allergy vaccines. Second-generation COP allergy vaccines are designed to boost and at the same time to modulate the immunogenicity of COPs towards a more TH1 rather than TH2 immune response. As part of this program, Anergis has entered into a research collaboration with Mymetics Corporation (OTCQB:MYMX), a pioneer and leader in the research and development of virosome-based vaccines.

Research to identify the most suitable formulation has already started, with initial results expected in Q1/2019. Subsequently, Anergis aims to proceed to the clinical evaluation of its second-generation COP allergy vaccines as soon as possible.

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About Anergis

Anergis SA is a Swiss biopharmaceutical company dedicated to the discovery and development of proprietary ultra-fast allergy immunotherapy products for the most prevalent allergies. Anergis was founded by Professor François Spertini, allergist at the University Hospital of Lausanne, Switzerland. Anergis raised over CHF 52 million from private and institutional investors, including BioMedInvest, Sunstone Capital, Renaissance PME and WJFS, Inc. Anergis SA is located in the Biopôle near Lausanne, Switzerland, a life sciences community bringing together industry and academia.

About Allergies

Allergies are the most prevalent and fastest growing chronic conditions in the industrialized world, affecting over 500 million people. The only curative therapy of allergies available today, known as "desensitization", "allergy shots" or "allergy immunotherapy" is the process of inducing tolerance to the allergen. It typically requires 3-5 years of treatment and exposes patients to the risk of serious side effects – in particular immediate (<30 min) anaphylactic reactions – which can be life-threatening. With its technology, Anergis is shaping the future of allergy treatment by developing therapeutic modalities that will only require 2 months of treatment - compared to 3 to 5 years with currently marketed products.

About Ultra-fast Allergy Immunotherapy Developments by Anergis

Anergis is focusing on novel, proprietary ultra-fast allergy immunotherapies based on Contiguous Overlapping Peptides (COPs). The first-generation lead product against birch pollen allergies, AllerT, contains three Bet v1 COPs and aluminum hydroxide as an adjuvant. With AllerT, Anergis has obtained clinical proof-of-concept of ultra-fast AIT with a single 2-month treatment course by demonstrating rapid and sustained



efficacy during the two seasons following treatment and long-term immune memory. Based on a comprehensive clinical data set established over the past years, Anergis has initiated a new research program to design a second generation of COP allergy vaccines with expected enhanced efficacy and improved tolerability.

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