



## **Anergis Closes CHF 5 Million Financing Round Extension to Conduct Large-Scale ATIBAR Trial with Ultra-Fast Allergy Immunotherapy AllerT**

- *Arrangements started for largest field trial ever conducted with an ultra-fast treatment for tree allergy*

EPALINGES, Switzerland, April 4, 2016 – Anergis, a company developing proprietary ultra-fast allergy immunotherapy, announced today that it has closed a CHF 5 million financing round extension with existing investors. In addition, the Company is preparing a Phase IIb clinical trial with its lead compound AllerT in patients with birch pollen allergy. The study is designed as a multicenter, double-blind, placebo-controlled, randomized trial to assess the efficacy and tolerability of two dosing regimens of **AllerT** In Adults with **B**irch Pollen **A**llergic **R**hinitis/Rhinoconjunctivitis (ATIBAR). ATIBAR is expected to start in fall 2016. With a total of 450 patients, ATIBAR will be the largest field-based trial conducted so far with an ultra-fast allergy treatment for tree allergy.

Most importantly, the ATIBAR trial is designed as a confirmatory efficacy trial with the statistical power necessary to meet both European and US FDA efficacy criteria for allergy immunotherapy products. Results will be expected in the third quarter of 2017.

“Our exploratory dose ranging trial with AllerT provided us with excellent new safety, tolerability and immunogenicity data. We are now preparing the ATIBAR trial as a confirmatory efficacy trial of the 50 µg dose and to verify that 10 µg is the lowest effective dose of AllerT” said Kim Simonsen, Chief Development Officer of Anergis.

“Thanks to the continued support of our investors, we have complemented our last financing round with a CHF 5 million extension and are now preparing AllerT for its future registration. Following a successful completion of the ATIBAR trial, we expect that only one more confirmatory efficacy Phase III trial will be required before registration,” added Vincent Charlon, Chief Executive Officer of Anergis.

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## **About Anergis**

Anergis SA is a Swiss-based biopharmaceutical company specializing in the discovery and development of novel, ultra-fast proprietary allergy immunotherapy products for the most prevalent allergies. Anergis' lead-product AllerT against birch pollen allergies is in Phase II clinical development. Two additional product candidates against ragweed pollen allergies (AllerR) and house dust mite allergies (AllerDM) are in preclinical development.

With the current financing round extension, Anergis has raised approximately CHF 52 million from private and institutional investors, including BioMedInvest, Renaissance PME, Sunstone Capital, and WJFS, Inc.

## **About Allergy**

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” or “Conventional Allergy Immunotherapy” (AIT), is the process of inducing tolerance to the allergen. It 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 treatment modalities that will only need 2 months of treatment instead of 3 to 5 years with currently marketed products.

## **About Ultra-fast Allergy Immunotherapy and AllerT**

AllerT is Anergis' ultra-fast allergy immunotherapy (AIT) against birch pollen allergy originating from the company's proprietary Contiguous Overlapping Peptide (COP) technology platform. COPs are long synthetic peptides reproducing the full amino acid sequence of one or more natural allergens, which are devoid of the IgE epitopes responsible for the risk of anaphylaxis during immunotherapy with allergens. COP Allergy Immunotherapy is “ultra-fast” because it only needs a single course of treatment of 2 months to induce long-lasting treatment effects without the need to repeat treatment the following year.

AllerT is today the only ultra-fast AIT treatment with demonstrated clinical efficacy in field-based trials for two consecutive pollen seasons and persistent statistically significant elevation in specific immunoglobulin G4 (IgG4) for four seasons, without any repeat treatment after the initial 2-month course.

In previous Phase II trials, the target doses of 50 µg and 100 µg AllerT showed similar field-based efficacy. To further explore the dose-efficacy relationship of AllerT, Anergis assessed lower doses (10 µg, 25 µg and again 50 µg vs placebo) in an exploratory trial in an environmental exposure chamber setting. This 213-patient trial demonstrated the dose-dependent immune responses and good tolerability at all



three AllerT dose levels (no grade 3 or higher allergic reactions, no serious and no severe side effects).

Studies of COPs targeting bee venom and birch pollen allergies in both animals and humans have consistently demonstrated excellent safety (i.e. no immediate allergic reaction) and immunogenicity (production of specific antibodies and cytokines against the original allergen and establishment of a long-term immune memory).

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