Anergis to Present New Data on Lead Compound AllerT at the 35th European Academy of Allergy and Clinical Immunology (EAACI) Congress 2016

- *Additional clinical Phase IIb data on the safety and efficacy of AllerT published in the* Journal of Allergy and Clinical Immunology
- *Composition-of-matter patent granted for AllerT by the European Patent Office*

EPALINGES, Switzerland, June 7, 2016 – Anergis, a company developing proprietary ultra-fast allergy immunotherapeutics, today announced upcoming presentations, the publication of new clinical data and the strengthening of the IP position of its proprietary, clinical-stage COP immunotherapy lead compound AllerT for the treatment of patients with allergy to birch pollen.

Presentations at the EAACI 2016

On June 13 and 14, Anergis will present new clinical data on AllerT at the 35th European Academy of Allergy and Clinical Immunology (EAACI) Congress (Vienna, Austria, June 11-15, 2016).

Two scientific presentations will feature new findings on the mechanism of action and on the safety and tolerability of AllerT, Anergis´ most advanced product based on the company´s proprietary Contiguous Overlapping Peptide (COP) platform.

The following scientific communications will be presented:

Presentation Title: "Bet v 1-derived contiguous overlapping peptides activate human B- and T Cell responses in human"
Presenter: Alexander Kettner
Time and Date: Monday, June 13, 2015, at 12:15pm CET
Session: Thematic Poster Session LB TPS 5: New Treatment Modalities in Immunotherapy
Abstract #: 1539

Presentation Title: "The emerging tolerability and safety profile of COP's (Contiguous Overlapping Peptides) containing both T and B cell epitopes in patients with birch allergic rhino-conjunctivitis"
Presenter: Kim Simonsen
Time and Date: Tuesday, June 14, 2016, at 10:30am CET
Session: Oral Abstract Session OAS 20: Safety and Efficacy of Allergen-specific Immunotherapy
Abstract #: A-716-0072-01932

Publication of Phase IIb Data in the *Journal of Allergy and Clinical Immunology*

Moreover, detailed clinical data from the first Phase IIb field-based study with AllerT were recently published online in the leading peer-reviewed *Journal of Allergy and Clinical Immunology.*[1] The trial examined the safety and efficacy of a two-month allergen-specific immunotherapy with COPs derived from the major birch pollen allergen Bet v1 in patients with allergic rhinoconjunctivitis in conditions of natural pollen exposure. The primary endpoint was the change in the combined rhinoconjunctivitis symptom and medication score (RSMS) vs placebo.

In this randomized, double-blind, placebo-controlled trial, 239 patients from 23 centers in 7 European countries received 5 preseasonal subcutaneous injections of either a placebo or AllerT at 50µg or 100µg doses.

The change in the RSMS was highly statistically significant vs the placebo in the 50µg group (p=0.015), and both active groups showed significant improvements in quality of life and nighttime nasal symptoms scores. AllerT injections were well tolerated, with a higher frequency of systemic adverse events in the 100µg group.

This study clearly demonstrated that only five injections in a 2-month treatment course with ultra-fast COP allergy immunotherapy provided a clinically meaningful reduction of seasonal allergy symptoms during the first season post treatment, without inducing more safety concerns than conventional SCIT injections. Furthermore, the treatment was shown to trigger a particularly strong IgG4 specific response, a crucial parameter of successful immunotherapy.

In 2015, Anergis released preliminary results from the second pollen season showing that the clinical response in the same group of patients was still present during the second season – without repeated treatment.[2]

New European Patent Granted on AllerT

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[1] Spertini F, DellaCorte G, Kettner A, de Blay F, Jacobsen L, Jutel M, Worm M, Charlon V, Reymond C, Efficacy of two months of allergen specific immunotherapy with Bet v 1-derived contiguous overlapping peptides in patients with allergic rhinoconjunctivitis: results of a Phase IIb study, *Journal of Allergy and Clinical Immunology* (2016), doi:10.1016/j.jaci.2016.02.044.

[2] Phase IIb follow-up trial of sustained efficacy of AllerT™ allergy vaccine during a second birch pollen season. Della Corte G.1, Jutel M.2, Jacobsen L.3, De Blay F.4, Worm M.5, Spertini F.6, Rak S.7, Kettner A.1, Reymond C.1, Charlon V.1

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In April 2016, Anergis was granted a composition-of-matter patent (patent no. 2393511) from the European Patent Office (EPO) on its AllerT product candidate for the treatment of patients with birch pollen allergy, thereby further broadening the geographical coverage of COP-based product patents.

“The Phase IIb trial described in the Journal of Allergy and Clinical Immunology is one of two main studies, which were integrated in this year’s EAACI presentation of the initial safety and tolerability profile of AllerT,” said Vincent Charlon, Chief Executive Officer of Anergis. "These consolidated data show that AllerT is not only efficacious for at least two yearly seasons without repeated treatment, but is also well tolerated across a broad range of doses tested. The ATIBAR trial currently in preparation is designed to deliver definitive efficacy and safety data at two doses of AllerT to identify the lowest effective dose prior to conducting the final Phase III confirmatory trial of AllerT."

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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 (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 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” 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 that reproduce 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 repeated 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 dose-dependent immune responses and good tolerability at all three AllerT dose levels (no grade 3 or higher allergic reactions, neither serious nor 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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