# Anergis Announces Top Line Results from Large-Scale ATIBAR Trial with Ultra-Fast Allergy Immunotherapy AllerT

- *Primary endpoint met: Combined Symptom and Medication Score in the AllerT 50 µg group is 7% lower than in the placebo group (p = 0.0047) over the entire birch pollen season*
- *Rhinoconjunctivitis Symptom Score in the AllerT 50 µg group is 14% lower than in the placebo group (p < 0.0001)*
- *Nighttime Nasal Symptom Score in the AllerT 50 µg group is 35% lower than in the placebo group (p<0.0001)*
- *Asthma Symptom and Medication Score in the AllerT 50 µg group is 29% lower than in the placebo group (p<0.0001)*

**EPALINGES, Switzerland, September 6th, 2017** – Anergis, a company developing proprietary ultra-fast allergy immunotherapy, announced today the top-line results from the ATIBAR trial, a Phase IIb field-based clinical trial with Anergis' lead compound AllerT for patients with birch pollen allergy.

A total of 421 patients were randomized at 38 European trial centers in Denmark, Finland, Germany, Lithuania, Norway, Poland, Slovakia and Sweden between September 2016 and January 2017. The trial met its objective to provide conclusive results, with well-balanced treatment groups, very few dropouts, and narrow confidence intervals of the observed treatment effects. The pollen exposure was satisfactory as assessed by the data collected from the pollen traps located close to the trial centers.

The trial met its primary endpoint with high statistical significance: the treatment effect of AllerT 50 µg vs placebo is a 7% improvement of the Combined Symptom and Medication Score (CSMS) with a 95% confidence interval of -2% to -11%, p=0.0047. This 7% improvement of the CSMS is driven by a 14% reduction of the Symptom Score (RSS) without meaningful difference of the Medication Score (RMS).

The primary endpoint results are supported by the main secondary endpoint mini-RQLQ (quality of life questionnaire) results (AllerT 50 µg -9% vs placebo, p=0.0526).

Additional strongly supportive data are significant reductions of the Asthma Symptom and Medication Score (-29%) and Nighttime Nasal Symptom Score (-35%), both p<0.0001.

The tolerability profile was similar to previous trials. Two grade 3 and two grade 4 systemic allergic reactions were reported in the AllerT 50 µg group.

"We are very thankful to the trial investigators, patients and all study personnel who contributed to the achievement of this high quality ATIBAR trial. We have met all our

objectives to produce highly reliable results with precise estimates of the treatment effect of AllerT," said Kim Simonsen, MD, Chief Development Officer of Anergis.

Vincent Charlon, PhD, CEO of Anergis, added: "While we are very satisfied with the trial performance and the high level of statistical significance achieved in this trial, we are surprised that the magnitude of efficacy is substantially lower than in our previous seasonal field trial (e.g. AN004T, CSMS difference from placebo -26%, p=0.01). We will continue analyzing and interpreting the data of the trial. In parallel, we have also started exploring strategic options including talking to external parties."

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## About Anergis

Anergis SA is a Swiss biopharmaceutical company dedicated to the discovery and development of novel, ultra-fast, proprietary allergy immunotherapy products for the most prevalent allergies. Anergis' lead-product against birch pollen allergies, AllerT, is in Phase II clinical development. Two additional product candidates against ragweed pollen (AllerR) and house dust mite allergies (AllerDM) are in preclinical development.
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", "allergy shots" or "Conventional Allergy Immunotherapy" (AIT), 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 only require 2 months of treatment - compared to 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 include 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 requires a single, 2-month course of treatment to induce long-lasting allergy symptom relief – without repeated treatment in following years.

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

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