

Anergis Starts Phase II Dose Ranging Trial with Birch Pollen Allergy Vaccine AllerT

- Dose assessment for upcoming Phase III trial

EPALINGES, Switzerland, December 11, 2014 – Anergis, a company developing proprietary ultra-fast allergy vaccines, today announced the start of a Phase II trial designed to finalize the dose selection for the Phase III study of AllerT. AllerT is Anergis' lead vaccine against birch pollen allergy that originated from the company's proprietary Contiguous Overlapping Peptide (COP) platform. COPs are pharmaceutical-grade, long-peptide immunotherapeutics designed for an ultra-fast, safe and long-lasting treatment of allergy patients.

The randomized, double-blind, placebo-controlled, 4-parallel-group trial will assess the dose response efficacy of AllerT across doses of 50 μ g, 25 μ g, 10 μ g compared to a placebo in an environmental exposure chamber (EEC). Approximately 180 birch pollen allergy patients will receive 5 subcutaneous injections over 2 months. All enrolled patients will be challenged with birch pollen prior to receiving AllerT or the placebo, and 4 weeks after the last injection.

The primary endpoint is the change in Total Rhinoconjunctivitis Symptom Scores (TRSS) from the baseline EEC challenge to the post-treatment EEC challenge. Secondary endpoints are the mean Total Nasal Symptom Scores (TNSS), Total Ocular Symptom Score (TOSS), Individual Nasal Symptom Scores (NSS) and Asthma Symptom Score (ASS), which will also be evaluated from the baseline EEC challenge to the post-treatment EEC challenge. The trial is being conducted in Canada, with results expected in the third quarter of 2015.

"In our previous field-based Phase II trials, we have seen that AllerT was equally efficacious at 100 μ g and 50 μ g doses," said Vincent Charlon, Chief Executive Officer of Anergis "We therefore want to further investigate the dose response of AllerT prior to launching the Phase III study."

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About Anergis

Anergis SA is a Swiss-based biopharmaceutical company specializing in the discovery and development of novel, proprietary allergy vaccines that target commercially attractive indications. Anergis' vaccines are based on its IP-protected Contiguous Overlapping Peptide (COP) technology. Allergies are the most prevalent and fastest growing chronic conditions in the industrialized world affecting over 500 million people.

Anergis' lead-product AllerT, a vaccine to treat birch pollen allergies, is due to enter



Phase III clinical development. Two additional vaccine candidates against ragweed pollen allergies (AllerR) and house dust mite allergies (AllerDM) are in preclinical development.

Anergis has raised around CHF 44 million from private and institutional investors, including BioMedInvest, Renaissance PME, Sunstone Capital, and WJFS, Inc.

About Anergis' COP Technology

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 ultra-fast desensitization, Anergis is shaping the future of allergy treatment. Anergis' vaccines are based on COPs which reproduce the complete amino acid sequence of the allergen in separate synthetic long peptides. COP allergy vaccines are pharmaceutical quality products that provide complete allergen sequences of all T cell epitopes, but do not cross-react with IgE, the antibody class responsible for eliciting allergic hypersensitivity. Therefore, COPs can be administered safely independent of MHC restriction and at high doses to induce tolerance to the allergen after only a few injections. This enables desensitization in 2 months as opposed to 3 years. Studies of COPs targeting bee venom and birch pollen allergies in both animals and humans have 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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