

Cytos Biotechnology updates on development of allergy vaccine

First promising results with QbG10 monotherapy in hay fever patients.

Initiation of three placebo-controlled, double-blind phase IIa clinical trials with 116 patients suffering from house dust mite allergy, hay fever, and atopic dermatitis.

Schlieren (Zurich), Switzerland, June 12, 2006 - Cytos Biotechnology AG (SWX:CYTN) reported today first promising results from a clinical trial with CYT003-QbG10, a potentially universal vaccine for the treatment of allergic diseases. The Immunodrug™ carrier QbG10 has previously shown powerful and sustained efficacy in a phase IIa clinical trial with patients suffering from allergic asthma and rhinitis due to house dust mite allergy when it was applied in combination with an approved house dust mite allergen extract (see Press Release, April 25, 2006). The increase achieved in the median allergen tolerance of a factor of 100, combined with a 100% median reduction of asthma symptoms and a 85% median reduction of rhinitis symptoms in daily life raised the question whether the treatment effect observed was due to an enhanced allergen-specific desensitization process or whether the QbG10 component itself effectively modified the patients' allergic status in an allergen-independent manner.

First results from an ongoing phase IIa clinical trial suggest that the powerful efficacy previously observed is conferred by the QbG10 component alone and that addition of a specific allergen extract may not be required. The present study assessed in an open label setting the exploratory efficacy of QbG10 monotherapy (designated CYT003-QbG10). 10 patients suffering from allergic rhinitis due to grass pollen allergy (hay fever) were treated with 6 weekly injections of CYT003-QbG10. Of these 10 patients, 5 could complete the study before onset of this year's grass pollen season. Treatment of these patients led to a marked improvement of allergy symptoms in the nasal provocation test ($p=0.03$), with an increase of the median allergen tolerance by a factor of 100. The remaining 5 patients cannot be tested during the current grass pollen season since environmental exposure to pollen interferes with the standardized test procedure applied.

Dr. Renner, CEO of Cytos Biotechnology, commented: "These are very promising first results suggesting that QbG10 indeed acts through an allergen-independent mechanism of action. This would clearly alter the profile of our vaccine candidate since QbG10 alone could be used as a universal vaccine for the treatment of a broad range of allergic diseases. Addition of specific allergens, which can be problematic particularly in those patients with moderate or severe disease, would no longer be required. To further investigate this exciting product candidate, we are now initiating three placebo-controlled and double-blind phase IIa clinical trials with a total of 116 patients suffering from hay fever, house dust mite allergy and atopic dermatitis, a common skin disease which is most likely caused by the same underlying disease mechanism."

Two of the studies are placebo-controlled, randomized and double-blind phase IIa clinical trials designed to assess safety, tolerability and exploratory efficacy of different formulations of CYT003-QbG10 in allergy patients. One study will recruit 40 patients suffering from mild to moderate rhinitis due to house dust mite allergy, while the second will recruit 40 patients suffering from the same

condition due to grass pollen allergy (hay fever). The third study is a placebo-controlled, randomized and double-blind phase IIa clinical trial that will assess safety, tolerability and exploratory efficacy of CYT003-QbG10 in 36 patients suffering from mild to moderate atopic dermatitis (eczema).

About allergic diseases and atopic dermatitis

Allergy as a whole is a widespread disease that ranges from mild hay fever to seriously life threatening forms of asthma and anaphylaxis. According to the World Health Organization, more than 20% of the world population suffers from allergic diseases (WHO, 2002). Allergies due to house dust mites and grass pollen are both very common. Whereas house dust mite allergy is a perennial allergy afflicting about 50% of all allergic patients (Clin Exp Allergy, 2004; 34:597), allergy to grass pollen is one of the most frequent causes of seasonal allergic rhinitis (hay fever) starting in spring every year and affecting 15-20% of the European population (WHO Europe, 2003).

An allergic reaction in general is caused by hypersensitivity of the immune system to a normally harmless substance, the allergen, causing a misdirected, so called Th2 type immune response. Today, three general approaches are pursued to relieve the symptoms of allergic diseases: avoidance of the allergen, prescription of medication that targets allergy symptoms, and specific immunotherapy, also known as desensitization, which is very time-consuming (3-5 years) but the only treatment currently available that reduces allergy symptoms for a longer period of time.

Atopic dermatitis (a certain type of eczema) is a common and chronic skin disease associated with an "allergic" Th2 type immune status of the patients. An estimated 20% of infants and young children experience disease symptoms and roughly 60% of those continue to have atopic dermatitis also in adulthood (NIH, 2003). The hypersensitivity reaction occurring in the skin causes chronic inflammation so that the skin becomes dry, itchy and scaly. Irritants (e.g. wool, soap), allergens and emotional stress can make disease symptoms worse and further trigger the overactive immune system. There is no cure available. Current medications include phototherapy, immunomodulators, corticosteroids, antihistamines, and immunosuppressants, some of which are associated with side-effects, especially upon long-term use.

About CYT003-QbG10

CYT003-QbG10 is a therapeutic vaccine in development for the treatment of allergy, asthma and atopic dermatitis. The vaccine consists of the Immunodrug™ carrier QbG10 which is comprised of the virus-like particle Qb filled with an immunostimulatory DNA sequence called G10. QbG10 is believed to enhance the establishment of a Th1 type immune response. As Th1 type immune responses have been shown to suppress "allergic" Th2 type immune responses, CYT003-QbG10 thus aims at induction of a strong Th1 type immune response. First promising results indicate that CYT003-QbG10 could thereby act through an allergen-independent mechanism of action so that it could become a causal and disease-modifying treatment for a broad range of allergic diseases. The vaccine candidate named CYT005-AllQbG10, which has been tested earlier for house dust mite allergy, is comprised of CYT003-QbG10 mixed to an approved house dust mite allergen extract.

Glossary

Allergen: a normally harmless substance that elicits a misdirected immune response.

Allergen tolerance: non-reactivity to a certain allergen or reactivity only up to the level of a predefined minimal symptom score.

Allergic rhinitis: a condition due to allergy that mimics a chronic cold. Rhinitis means "irritation of the nose".

Anaphylaxis: an acute and life-threatening reaction of the immune system to specific stimuli. If untreated, it can result in shock, respiratory and cardiac failure, and death.

Asthma: a chronic inflammatory disorder of the airways leading to recurrent episodes of wheezing, breathlessness, chest tightness and cough in susceptible individuals.

Atopic dermatitis: a chronic skin disease; a certain type of eczema. "Atopic" refers to a group of diseases with an inherited tendency to develop other allergic conditions (e.g. asthma and hay fever). "Dermatitis" means inflammation of the skin.

Desensitization: a certain form of immune therapy applied to treat allergy.

Disease-modifying: in contrast to symptomatic treatment, a disease-modifying treatment aims at addressing the cause of disease and modifying the disease progression.

Double-blind: a set-up often used in clinical trials where neither the doctor nor the patient knows if placebo or the active drug is applied.

Eczema: a general term for several types of inflammation of the skin including e.g. allergic contact eczema and atopic dermatitis.

Efficacy: strength, effectiveness; the ability of a drug to control or cure an illness.

Formulation: the method and process of selecting the components of a mixture and the product of such a process. For drugs the term usually describes the way the final drug is prepared and applied.

Hay fever: seasonal allergic rhinitis.

Hypersensitivity: an excessive immune reaction.

Nasal provocation test: a commonly used test to monitor the allergic status of an individual. Standardized aqueous allergen solutions are applied to the nasal mucosa in increasing concentrations and the score of predefined allergic symptoms is recorded.

Open label: a set-up used in clinical trials where the doctor and the patient know what substance is administered.

Phase IIa: a clinical trial that examines a new drug candidate's safety and exploratory efficacy in the targeted population and can involve between 10 and 100 patients.

Placebo: dummy medical treatment.

QbG10: Cytos Biotechnology's Immunodrug™ carrier Qb filled with the immunostimulatory DNA sequence G10.

Randomized: random assignation of clinical trial participants to different treatment groups.

Th1 and Th2 type immune responses: describe a subset of T helper cell responses. T helper cells are a subset of T cells that secrete a variety of mediators (cytokines) playing a role in activation of other immune cells. A Th1 type immune response is usually induced by viral infection, or also by potent vaccination. A Th2 type immune response usually manifests an allergic reaction.

Therapeutic vaccine: a preparation of molecules (antigens) that aims at inducing an immune response to such antigens with the goal to modulate an ongoing disease process.

About Cytos Biotechnology AG

Cytos Biotechnology AG is a public Swiss biotechnology company that specializes in the discovery, development and commercialization of a new class of biopharmaceutical products – the Immunodrugs™. Immunodrugs™ are intended for use in the treatment and prevention of common chronic diseases, which afflict millions of people worldwide. Immunodrugs™ are designed to instruct the patient's immune system to produce desired therapeutic antibody or T-cell responses that modulate chronic disease processes. Taking advantage of the high flexibility of its Immunodrug™ platform, Cytos Biotechnology has built a pipeline of 26 different Immunodrug™ candidates in various disease areas, of which 7 are currently in clinical development. The Immunodrug™ candidates are developed both in-house (23) and together with Novartis (1) and Pfizer Animal Health (2). Founded in 1995 as a spin-off from the Swiss Federal Institute of Technology (ETH) in Zurich, the company is located in Schlieren (Zurich). Currently, the company has 131 employees. Cytos Biotechnology AG has been listed on the SWX Swiss Exchange (SWX:CYTN) since October 2002.

For further information please contact:

Dr. Claudine Blaser
Director Corporate Communications

Phone: +41 44 733 47 20

Fax: +41 44 733 47 18

e-Mail: claudine.blaser@cytos.com

Website: www.cytos.com

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