

Placebo-controlled phase IIa study with the immunotherapeutic CYT003-QbG10 shows significant improvement of allergy symptoms in hay fever patients

Schlieren (Zurich), Switzerland, March 13, 2007 - Cytos Biotechnology AG (SWX:CYTN) reported today positive results from a phase IIa study with CYT003-QbG10, an immunotherapeutic product candidate for the treatment of allergic diseases. The study included 40 patients suffering from mild to moderate allergic rhinitis due to grass pollen allergy (hay fever). The trial investigated in a double-blind setting the safety, tolerability and exploratory efficacy of two different formulations of CYT003-QbG10 monotherapy to placebo, and in an open-label setting a CYT003-QbG10 formulation comprising a low dose of grass pollen extract. Exploratory efficacy of CYT003-QbG10 was determined by assessing the allergic disease status of the patients before and after treatment by the conjunctival provocation test, yielding a symptom score ranging from 0 to 15 points.

All formulations of CYT003-QbG10 tested were safe and well tolerated. Treatment with CYT003-QbG10 monotherapy led to a significant ($p < 0.05$) improvement of allergy symptoms in the conjunctival provocation test when compared to placebo. A reduction of the median symptom score from 9 points pre-treatment to 5 points post-treatment was achieved (for placebo: 9 points pre-treatment to 8 points post-treatment). For the formulation of CYT003-QbG10 plus grass pollen extract, the median symptom score was reduced from 9 points pre-treatment to 4 points post-treatment, whereas for the formulation of CYT003-QbG10 plus alum, no significant reduction was observed when compared to placebo.

Dr. Wolfgang Renner, CEO of Cytos Biotechnology, commented: "These results mark a further important milestone in the development of CYT003-QbG10 monotherapy and confirm prior open-label observations of efficacy of this product in a double-blind, placebo-controlled setting. At this stage, we are assessing various parameters of this promising Immunodrug™ candidate such as different formulations, doses, and treatment regimens. Each of the currently ongoing and planned studies is aimed at gaining wider experience for this novel treatment approach and to bring us closer towards a causal and disease-modifying therapy for a broad range of allergic diseases."

Cytos Biotechnology will host a conference call and Q&A session today, Tuesday, March 13, 2007 at 9.30 am CET to discuss the study findings.

To access the conference call, please dial the following numbers:

Europe	+41 91 610 56 00
U.S.	+1 866 291 41 66
U.K.	+44 207 107 06 11

The conference call will be held in English and will also be accessible by webcast on the internet. You may follow the call live or have it replayed later on demand. To access the webcast and the presentation, please follow the link provided on our homepage www.cytos.com. The presentation slides will be available for download 30 minutes prior to the conference call.

About the phase IIa study and the analysis

The randomized, double-blind and placebo-controlled phase IIa study included 40 male and female patients aged 18 to 65 and suffering from mild to moderate seasonal allergic rhinitis due to grass pollen allergy. Upon entry into the study, the allergic status of the individual participants was recorded by the conjunctival provocation test, a commonly used allergy test. The study participants were randomized into 4 treatment groups with 10 patients each and received 6 weekly injections of either i) 300 µg CYT003-QbG10, ii) 300 µg CYT003-QbG10 plus Alum, iii) placebo (PBS or Alum), or iv) 300 µg CYT003-QbG10 plus grass pollen extract (this last group was handled exploratory and open-label). Two weeks after the last dose, the allergic status of the patients was again assessed by the conjunctival provocation test. All 40 patients were included into the analysis.

About CYT003-QbG10

CYT003-QbG10 is an immunotherapeutic product in development for the treatment of allergy, asthma and atopic dermatitis. It consists of the Immunodrug™ QbG10 which is comprised of the virus-like particle Qb filled with a synthetic immunostimulatory DNA sequence called G10. CYT003-QbG10 is designed to induce a potent Th1 type immune response in order to suppress an "allergic" Th2 type immune response. As initial clinical observations indicate, CYT003-QbG10 could thereby act by an allergen-independent mechanism of action so that it has potential as a causal and disease-modifying treatment for a broad range of different allergic diseases. CYT003-QbG10 is currently being studied in several clinical trials for the treatment of allergic rhinitis, asthma and atopic dermatitis.

About allergic diseases

Allergy as a whole is a multi-faceted disease and clinically manifests in various allergic disorders including allergic rhinitis, asthma, atopic dermatitis and food hypersensitivity. It is an exaggerated reaction by the patient's immune system to a normally harmless substance such as various environmental proteins present in pollen, animal excrements, or food. According to the World Health Organization, more than 20% of the world population suffers from allergic diseases (WHO, 2002). Seasonal allergic rhinitis due to grass pollen (commonly known as hay fever) is very common and affects 15-20% of the European population (WHO Europe, 2003). Three general approaches are commonly being pursued to relieve the symptoms of allergic diseases: avoidance of the allergen, prescription of medication that targets disease symptoms, and conventional immunotherapy, also known as desensitization. The latter is the only disease-modifying treatment available, however, it is applicable only for some defined allergies, is time-consuming (3-5 years) and inconvenient for the patients. Therefore, a significant unmet medical need remains for allergic disease treatment.

Glossary

Allergic rhinitis: a condition due to allergy that mimics a cold. Rhinitis means "inflammation of the nasal mucous membranes".

Alum: commonly used adjuvant in human applications. An adjuvant is administered to enhance an immune response.

Atopic dermatitis: a chronic skin disease; a certain type of eczema. Is accompanied by an inherited tendency to develop allergic diseases.

Conjunctival provocation test: a commonly used allergy test to monitor the allergic disease status of an individual.

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

DNA: deoxyribonucleic acid; genetic information of an organism.

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

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

Grass pollen extract: a mixture of allergenic components from grass pollen.

Hay fever: seasonal allergic rhinitis.

Immunotherapy / immunotherapeutic: a therapy aimed at activation of the immune system to modulate a certain disease process. Conventional immunotherapy for allergic diseases, also termed desensitization, is performed with allergen. CYT003-QbG10 appears to act differently, namely through an allergen-independent mechanism of action in the absence of an added allergen.

Median: a term used in the statistical analysis of a set of numbers; it relates to or constitutes the middle value in a distribution. 50% of the values are above and 50% below the median.

Monotherapy: treatment with one drug as opposed to combination therapy. Here the term refers to treatment with CYT003-QbG10 alone in contrast to a regimen where CYT003-QbG10 is combined to an allergen extract.

Open-label: a set-up used in clinical trials where the doctor and the patient know what substance is administered; in contrast to e.g. double-blind, placebo-controlled studies, where neither the doctor nor the patient have this knowledge.

Phase IIa: a clinical trial that examines a new drug candidate's safety and exploratory efficacy and may include between 10 and 100 patients.

Placebo: dummy medical treatment.

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

Regimen: describes a treatment schedule according to which a drug is administered.

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

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 different Immunodrug™ candidates in various disease areas, of which 6 are currently in clinical development. The Immunodrug™ candidates are developed both in-house and together with Novartis and Pfizer Animal Health. 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 130 employees. Cytos Biotechnology AG has been listed on the SWX Swiss Exchange (SWX:CYTN) since October 2002.

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