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Cytos Biotechnology presents analysis of patient diaries including six month follow-up data from phase II study with CYT003-QbG10 monotherapy for the treatment of allergic diseases

- Patients treated with CYT003-QbG10 monotherapy had significantly lower average combined symptom and medication scores both two and six months after start of treatment than patients on placebo
- In the subgroup of patients with asthma (52 out of 80), the average combined asthma symptom and medication score was significantly lower in CYT003-QbG10 treated patients than in placebo treated patients two months after start of treatment

Schlieren (Zurich), Switzerland, January 13, 2009 – Cytos Biotechnology Ltd (SIX:CYTN) announced today new data from a double-blind, placebo-controlled, multicentre, phase II study with CYT003-QbG10 monotherapy for the treatment of allergy and asthma. The study included 80 patients suffering from house-dust mite and/or cat allergy, of whom 52 also had allergic asthma. First study results were published on July 10, 2008 and were presented at the Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology (ACAAI) in Seattle, USA, on November 9, 2008. These results showed that six weekly injections of CYT003-QbG10 were safe, well tolerated and significantly reduced rhinoconjunctivitis symptoms in daily life compared to placebo.

Allergy diaries served as an additional read-out parameter of this study and patients filled in diary cards about their daily nasal, conjunctival, and bronchial symptoms as well as the use of rescue medication for two consecutive weeks at different time points. The study participants returned these diary cards for analysis after the recently completed six month follow-up visits.

The average combined symptom and medication score (ACS) based on diary card records is the standard clinical parameter for the assessment of allergic disease severity and recommended by the World Allergy Organisation (WAO)¹. During weeks 8 and 9 after start of treatment, the ACS was 62% lower in patients treated with CYT003-QbG10 (ACS=0.19) than in patients on placebo (ACS=0.50), $p=0.002$; representing reductions from baseline of 51% and 11%, respectively. During weeks 25 and 26, the ACS was 66% lower in CYT003-QbG10 treated patients (ACS=0.14) than in patients on placebo (ACS=0.41), $p=0.016$.

A subgroup analysis of the 52 patients with allergic asthma revealed during weeks 8 and 9 a 66% lower average combined asthma symptom and medication score (ACAS) in patients treated with CYT003-QbG10 (ACAS=0.15) than in patients on placebo (ACAS=0.44), $p=0.02$; representing reductions from baseline of 72% and 15%, respectively. During weeks 25 and 26, the ACAS was 55% lower in CYT003-QbG10 treated patients (ACAS=0.13) than in patients on placebo (ACAS=0.29), $p=0.09$.

In addition, the six month follow-up data confirmed the excellent safety and tolerability profile of CYT003-QbG10.

Dr. Wolfgang Renner, CEO of Cytos Biotechnology, commented the new study results: "These new data further support the concept of CYT003-QbG10 monotherapy in allergic rhinoconjunctivitis and additionally provide us with a strong rationale to extend our development activities with this product candidate towards the important indication of allergic asthma. Our phase IIb study with 300 patients suffering from allergic rhinoconjunctivitis has started in December 2008 and, on top of this, we are on track to start a new phase II study with CYT003-QbG10 monotherapy in 60 patients suffering from persistent allergic asthma in the first half of this year. In both indications exists a significant unmet medical need and disease-modifying therapies which are allergen-independent are lacking altogether. CYT003-QbG10 which activates toll-like-receptor 9 could satisfy these needs."

The detailed study results will be presented at an upcoming scientific conference.

About CYT003-QbG10

CYT003-QbG10 is an immunotherapeutic product in development for the treatment of allergy and asthma. It is based on Cytos Biotechnology's modified Immunodrug™ platform, which applies immunostimulatory DNA sequences to induce targeted T cell responses. The immunotherapeutic encompasses the virus-like particle Qb, which is filled with the immunostimulatory DNA sequence G10 – a synthetically produced stretch of DNA originally derived from bacteria. This DNA sequence is recognized by so called toll-like receptors, an evolutionary ancient class of receptors that detect microbial patterns and serve as the first line of defense of the immune system. CYT003-QbG10 aims to alter the immunological milieu and the allergic immune cell responses to ameliorate disease symptoms. In contrast to current immunotherapy approaches, which are all based on allergen components, CYT003-QbG10 is free of allergen and is thought to act through an allergen-independent mechanism. The use of a single allergen-independent agent would not only simplify treatment for multiple allergies but also improve tolerability by avoiding allergen-induced side effects.

About allergic diseases

Allergy as a whole is a multi-faceted disease and manifests itself clinically in various allergic disorders including allergic rhinoconjunctivitis, asthma, eczema 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, dust mite faeces, or food. Allergy is a very common chronic disease, and its prevalence has increased dramatically within the last few decades. Today, more than 20% of the world population suffers from allergic diseases², and Europe alone has 80 million allergy sufferers³. House dust mites and cats represent the two most important allergen sources for perennial allergies.

There are three general approaches being pursued today to relieve the symptoms of allergic diseases: avoidance of the allergen whenever possible; prescription of medication that targets disease symptoms; and conventional immunotherapy, also known as desensitization. Symptomatic medication available only offers short-term amelioration of the disease. For patients this may mean chronic use of corticosteroids and antihistamines – often with multiple daily doses. Conventional immunotherapy, on the other hand, is very time-consuming (3-5 years) and, with up to 80 allergen injections, it is also inconvenient for the patient, so that only few allergy sufferers take advantage of this therapy.

For further information please contact:

Claudine Blaser, PhD

Director Corporate Communications, Cytos Biotechnology Ltd

Phone: +41 44 733 47 20

Fax: +41 44 733 47 18

e-Mail: claudine.blaser@cytos.com

Website: www.cytos.com

References

- 1 Recommendations for standardization of clinical trials with allergen-specific immunotherapy for respiratory allergy. A statement of a World Allergy Organization (WAO) taskforce; *Allergy*, 2007; 62:317, and Assessment of combined symptom and medication scores for rhinoconjunctivitis immunotherapy clinical trials; *Allergy*, 2007; 62:1023.
- 2 World Health Organization; *Prevention of Allergy and Allergic Asthma*, January 2002.
- 3 GA²LEN - Global Allergy and Asthma European Network, www.ga2len.net, 2008.

About Cytos Biotechnology

Cytos Biotechnology Ltd 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 diversified pipeline of different Immunodrug™ candidates in various disease areas, of which five are currently in clinical development. The Immunodrug™ candidates are developed both in-house and together with Novartis, Pfizer, 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 133 employees. Cytos Biotechnology Ltd is listed on the SIX Swiss Exchange (SIX:CYTN).

Glossary

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

Allergic asthma: chronic inflammation and obstruction of the airways of the lungs caused by exposure to allergens.

Average combined symptom and medication score (ACS): symptoms and concomitant medication use during the study are recorded on individual diary cards during a defined period of time. As a clinical outcome measure, the World Allergy Organization (WAO) recommends to utilize the average of the scores achieved for total allergy symptoms and medication use. When applied to the subgroup of asthma patients in this study, the average score was defined as average combined asthma symptom and medication score (ACAS).

Bronchial: relating to the air passages to and from the lungs including the bronchi and the bronchioles.

Conjunctival: relating to the conjunctiva, the mucous membrane that lines the inner surface of the eyelid and the exposed surface of the eyeball.

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

Immunostimulatory: able to stimulate the immune system.

Immunotherapy / immunotherapeutic: a therapy / a medication aimed at activation of the immune system to modulate a certain disease process.

Monotherapy: treatment with one drug as opposed to combination therapy. Here the term refers to treatment with QbG10 alone (i.e. CYT003-QbG10) in contrast to an earlier regimen where QbG10 was combined to allergen extract (i.e. CYT005-AllQbG10).

Phase II/IIb: clinical trial that examines a new drug candidate's safety, tolerability and exploratory efficacy in patients.

Placebo: dummy medical treatment.

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

Rescue medication: during the study, patients are provided access to specified medications to alleviate allergy symptoms if needed.

Rhinoconjunctivitis: combination of rhinitis (inflammation of the nasal mucosa) and conjunctivitis (inflammation of the mucous membrane of the eye).

T cell: immune cell playing an important role in cell-mediated immunity. One differentiates various subgroups such as cytotoxic (killer) T cells, T helper (Th) cells and regulatory T cells.

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