

**MEDIA RELEASE - MEDIENMITTEILUNG - COMMUNIQUE AUX MEDIAS**

## Cytos Biotechnology reports positive results from placebo-controlled phase IIa study in patients suffering from house dust mite allergy

Schlieren (Zurich), Switzerland, May 15, 2007 - Cytos Biotechnology AG (SWX:CYTN) reported today positive results from a multi-centre and placebo-controlled phase IIa study with different formulations of 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 house dust mite allergy and assessed in a double-blind setting the safety, tolerability and exploratory efficacy of CYT003-QbG10 monotherapy, CYT003-QbG10 combined with a low dose of house dust mite allergen extract (designated CYT005-AllQbG10), allergen extract alone and placebo. Exploratory efficacy was determined by evaluating the allergic disease status of the patients before and after treatment by the conjunctival provocation test.

Both formulations of CYT003-QbG10 tested were safe and well tolerated. The table below summarizes on the first results obtained two weeks after the last dose. A statistically significant increase in the median allergen tolerance against baseline was observed only in the two treatment arms which comprised QbG10 (i.e. CYT003-QbG10 monotherapy and CYT005-AllQbG10), whereas none of the intergroup comparisons achieved statistical significance.

|                                                        | <b>CYT003-QbG10</b><br>n=10 | <b>CYT005-AllQbG10</b><br>n=10 | <b>Placebo</b><br>n=10 | <b>Allergen</b><br>n=10 |
|--------------------------------------------------------|-----------------------------|--------------------------------|------------------------|-------------------------|
| Increase of median allergen tolerance against baseline | factor of 10                | factor of 10                   | factor of 1            | factor of 10            |
| p-value                                                | <0.05                       | <0.05                          | n.s.                   | n.s.                    |

Dr. Wolfgang Renner, CEO of Cytos Biotechnology commented: "With each study we gain a deeper understanding of the activity of QbG10 in allergic diseases. If we look at the entire data set of the 80 allergic patients treated so far with QbG10 in the different studies, we can see the following picture: QbG10 seems to be active as a monotherapy; however, combination with an allergen extract at a standard dose appears to enhance the therapeutic effect. The highest efficacy was achieved when QbG10 was combined with a dose of allergen extract usually applied in conventional desensitization therapy, i.e. a 10-times higher dose than the one tested in this present study. In a next clinical trial we will test higher doses of CYT003-QbG10 monotherapy and compare the safety and efficacy profile directly with the most promising product formulations of CYT005-AllQbG10 in order to select the best product candidate for late stage development."

### **CYT003-QbG10 Conference Call and Webcast**

Cytos Biotechnology will host a conference call and Q&A session today, Tuesday, May 15, 2007 at 10 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](http://www.cytos.com). The presentation slides will be available for download 30 minutes prior to the conference call.

Among other projects, Cytos Biotechnology will also discuss its allergy program at the company's upcoming R&D day on Wednesday, June 20, 2007 at 2 pm (CET) at the company's premises in Schlieren.

### **About the phase IIa study and the analysis**

The multi-centre, 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 perennial allergic rhinitis due to house dust mite 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 subcutaneous injections of either i) 300 µg CYT003-QbG10 alone, ii) 300 µg CYT003-QbG10 plus a low dose of house dust mite allergen extract (designated CYT005-AllQbG10), iii) a low dose of house dust mite allergen extract alone, or iv) placebo. The house dust mite allergen dose administered in treatment arms ii) and iii) was 10-times lower than that usually applied in conventional desensitization therapy. Two weeks after the last dose, the allergic status of the patients was again assessed by the conjunctival provocation test, which served as the primary efficacy parameter of the study. 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 as a disease-modifying treatment and aims to induce a potent Th1 type immune response in order to suppress an "allergic" Th2 type immune response. An earlier, open-label phase IIa study with CYT003-QbG10 combined with an allergen extract of house dust mites at a standard dose showed excellent long-term efficacy in patients allergic to dust mites. Furthermore, a placebo-controlled phase IIa study with CYT003-QbG10 showed significant improvement of allergy symptoms in hay fever patients. CYT003-QbG10 is currently being studied in clinical trials for the treatment of allergic rhinitis 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, dust mite faeces, or food. According to the World Health Organization, more than 20% of the world population suffers from allergic diseases (WHO, 2002). Allergy to house dust mites is one of the most common causes of allergic disease worldwide and it is estimated that nearly 50% of allergic people are sensitized to dust mite allergens (Clin Exp Allergy, 2004;34:597). Dust mite allergy frequently starts with symptoms of rhinitis, but over the longer term many patients may develop symptoms of asthma. Today, 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 time-consuming (3-5 years) and inconvenient for the patients. Therefore, a significant unmet medical need remains for allergic disease treatment.

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**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.*

**Glossary**

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 cold. Rhinitis means "inflammation of the nasal mucous membranes".

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 to modify disease progression.

DNA: deoxyribonucleic acid; genetic information of an organism.

Desensitization: conventional immunotherapy applied to treat allergies. Requires frequent injections (50-80 injections) of allergen under the skin over several years.

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.

House dust mite allergen extract: a mixture of allergenic components from house dust mites.

Immunotherapeutic: a product aimed at activation of the immune system to modify and interfere with a certain disease process.

Median: a term used in the statistical analysis of a set of numbers; 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 (i.e. CYT005-AllQbG10).

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.

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

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.

This foregoing press release may contain forward-looking statements that include words or phrases such as "seem", "appear", "will", "designed", "aim", "may", "intend" or other similar expressions. These forward-looking statements are subject to a variety of significant uncertainties, including scientific, business, economic and financial factors, and therefore actual results may differ significantly from those presented. There can be no assurance that any other therapeutic entities will enter clinical trials, that clinical trial results will be predictive for future results, that therapeutic entities will be the subject of filings for regulatory approval, that any drug candidates will receive marketing approval from the U.S. Food and Drug Administration or equivalent regulatory authorities, or that drugs will be marketed successfully. Against the background of these uncertainties readers should not rely on forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments. This document does not constitute an offer or invitation to subscribe or purchase any securities of Cytos Biotechnology AG.