

Placebo-controlled phase II study shows CYT003-QbG10 is safe and efficacious for the treatment of allergic asthma

- All patient reported outcome measures were continuously and significantly improved vs. placebo from week 6 onward to the end of the study
- Lung function objectively assessed by spirometry (FEV₁) was continuously and significantly improved vs. placebo from week 6 onward to the end of the study

Schlieren (Zurich), Switzerland, May 21, 2010 – Cytos Biotechnology Ltd (SIX:CYTN) reported today top line results from a double-blind, placebo-controlled, multicenter phase II study to assess clinical efficacy of CYT003-QbG10 in persistent allergic asthma bronchiale. The study enrolled 63 allergic asthma patients requiring long term treatment with inhaled corticosteroids. Patients received 7 injections of 900 µg QbG10 or placebo and were monitored over a period of 12 weeks.

During a run-in phase before start of treatment with QbG10 or placebo, the patients were converted to and stabilized on a standardized corticosteroid therapy with beclamethasone. Four weeks after starting treatment with QbG10 or placebo, the dose of corticosteroid was reduced by 50%. Then, when possible, four weeks later it was further reduced to zero. Both arms of the study followed this steroid reduction and there were no significant differences in steroid use at any time point. During the entire 12 week study period, daytime and nighttime asthma symptoms and use of a standardized relief medication (sultanol spray, a short-acting beta 2 agonist) were recorded in electronic patient diaries. In addition, lung function was assessed on each visit by spirometry which measures forced expiratory volume in one second (FEV₁).

All patient reported outcome parameters were significantly improved vs. placebo during each week from week 6 onwards to the end of the study at week 12 (ITT analysis, LOCF). At week 12, the average daytime and nighttime asthma symptom score had increased (i.e. disease worsened) by +29% for the placebo group, while it decreased (i.e. disease improved) by -33% for QbG10 treated subjects (p=0.01). Use of relief medication had increased on average by +106% for the placebo group, while it remained stable for the QbG10 group (-4%) (p=0.01). The average combined symptom and medication score worsened by +71% for the placebo group, while it improved by -17% in the QbG10 group (p=0.006). In summary, the withdrawal of corticosteroid as expected led to a worsening of the disease for placebo. In contrast for patients treated with QbG10 their condition improved. This improvement came despite the fact the patients either no longer used or strongly reduced their intake of corticosteroids.

A subgroup analysis of the patients who completely ceased inhaling corticosteroids after week 8 (22 on QbG10, 21 on placebo) allows a comparison of patient reported outcome after QbG10 treatment (i.e. during week 9 to 12) with beclamethasone therapy at baseline (i.e. the two weeks before QbG10 or placebo therapy were initiated). The substitution of beclamethasone by QbG10 led in these patients to a reduction of asthma symptoms by -37% (p=0.02), a reduction of sultanol intake by -30% (n.s.) and a reduction of the combined symptom and medication score by -34% (p=0.07). The corresponding values under placebo treatment were +6%, +58%, and +33%. This analysis suggests that treatment with QbG10 may result in a therapeutic effect that is as good, or even better than inhaled corticosteroid therapy.

Objective lung function measurement by spirometry reflected the strong improvement seen in the patient reported outcome parameters. Here, the forced expiratory volume in one second (FEV₁) was significantly improved vs. placebo at each weekly measurement from week 6 onwards until the end of the study at week 12 (ITT analyses, LOCF). At week 12, the FEV₁ had decreased for those on placebo by an average of 251 ml (-8.4%) while it remained stable for those on QbG10 treatment (-18.5 ml, -0.6%) (p=0.01).

Treatment was safe and well tolerated. Local injection site reactions of mostly mild to moderate intensity and two instances of headache were the only adverse events of suspected relationship with treatment that occurred in more than one patient.

Dr. Wolfgang Renner, CEO of Cytos commented the study results: "Asthma and allergies contribute greatly to the growing burden of chronic diseases that inflict our societies and have reached epidemic proportions worldwide; principally as a result of increased industrialization and urban living. Allergic asthma is a significant cause of morbidity and mortality, often affecting individuals early in their lives. With QbG10, we are within reach of a product with the potential to become the first causally acting and disease modifying therapy for allergic diseases addressing important unmet medical need.

QbG10 has shown to rapidly and strongly improve both objective and patient reported outcome measures of disease. The extent to which this has been achieved may position QbG10 as a new standard therapy for allergies and asthma. Achievement of this outstanding clinical result in the major disease area of asthma builds on our earlier success with this product candidate in allergic rhinitis and provides compelling evidence that Cytos' VLP platform can confer significant therapeutic benefit in chronic illnesses burdening the world's population."

Conference call today at 3.00 pm (CET)

Cytos Biotechnology will host a conference call and Q&A session today, Friday, May 21, 2010 at 3.00 pm (CET) to discuss the study results.

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 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 the company's home page www.cytos.com. The conference will be held in English and the presentation slides will be available for download 30 minutes prior to the 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 allergic diseases. In a previous phase IIb study in 300 patients with allergic rhinoconjunctivitis, QbG10 was safe, well tolerated and efficacious in lowering the combined symptom and medication score as well as in improving quality of life with rhinoconjunctivitis.

About allergic asthma bronchiale

Asthma bronchiale (usually referred to as asthma) is a chronic inflammatory disorder of the airways that causes breathlessness, chest tightness, coughing and wheezing in susceptible individuals. Allergic asthma is the most common form of asthma affecting around 150 million people worldwide¹. It is further the most common chronic disease among children. Allergic asthma is triggered by inhaled allergens such as dust mite allergen, animal dander or pollen. Currently, there are three general approaches being pursued to relieve the clinical manifestations of allergic asthma: avoidance of the allergen, symptomatic treatment to alleviate acute consequences of allergen exposure or chronic consequences of inflammatory processes, and conventional immunotherapy, also known as desensitization, which is the only treatment available that has a disease-modifying long-term effect. Conventional immunotherapy, however, is time-consuming (3-5 years) and with up to 80 allergen injections also inconvenient for the patient. In addition, there is a risk of serious side-effects in response to allergen exposure, which can even include anaphylaxis.

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Reference

¹ World Health Organization; Asthma – Key facts; Fact Sheet No. 307, May 2008, and Asthma and Allergy Foundation of America (AAFA), Asthma facts and figures, www.aafa.org, 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 Immunodrug™ candidates in various disease areas, of which six 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 spinoff from the Swiss Federal Institute of Technology (ETH) in Zurich, the Company is located in Schlieren (Zurich). Currently, the Company has 81 full-time 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.

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

Desensitization: certain form of immunotherapy used in allergy treatment.

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 patients know if placebo or the active drug is applied.

FEV₁: a lung function test, which measures forced expiratory volume in one second (FEV₁).

Inflammatory: substance evoking inflammation.

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

Immunostimulatory: able to stimulate the immune system.

ITT analysis: an intention to treat (ITT) analysis is an analysis based on the initial treatment intent, not on the treatment eventually administered. It includes all randomized patients and is intended to avoid various misleading artifacts that can arise in intervention research.

LOCF: means "last observation carried forward". Missing values are replaced by the last observed value of this variable. If a patient deviated from the corticosteroid reduction paradigm, the last value measured under the correctly followed ICS reduction scheme was carried forward.

Persistent: refers to a defined classification of asthma disease severity. Patients in this foregoing study suffer daily from asthma symptoms if untreated.

Phase II: a clinical trial that examines a new drug candidate's safety and preliminary efficacy in the targeted population and involves approximately 50-300 people.

Placebo: dummy medical treatment.

QbG10: the Immunodrug™ Qb filled with the synthetically produced immunostimulatory DNA sequence G10.

This foregoing press release may contain forward-looking statements that include words or phrases such as "expected", "suggest", "may", "become", "will", "intended", "designed" 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 further 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 Ltd.