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Cytos Biotechnology initiates phase IIa study with CYT003-QbG10 monotherapy in patients with allergic asthma bronchiale

Schlieren (Zurich), Switzerland, April 21, 2009 – Cytos Biotechnology Ltd (SIX:CYTN) announced today that it has initiated a phase IIa clinical study with CYT003-QbG10, an immunotherapeutic product candidate for the allergen-independent treatment of allergy and asthma. The study is a randomized, double-blind, placebo-controlled, multicentre study to evaluate the safety, tolerability and exploratory efficacy of CYT003-QbG10 in 60 patients with persistent allergic asthma bronchiale. First results are expected to be available in H1 2010.

CYT003-QbG10 is based on Cytos Biotechnology's modified Immunodrug™ platform, which encompasses the virus-like particle Qb filled with the immunostimulatory DNA sequence G10. CYT003-QbG10 is designed as a disease-modifying treatment and aims to alter the immunological milieu and the allergic immune cell responses to ameliorate disease symptoms. In contrast to conventional 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 an allergen-independent agent would not only simplify treatment for multiple allergies but may also allow application in patients with severe allergies and asthma for whom conventional immunotherapy approaches are not recommended as exposure to allergens may cause serious side-effects. In a recent phase II study CYT003-QbG10 showed a beneficial treatment effect in a subgroup of patients with allergic asthma, thus providing a rationale for further development of CYT003-QbG10 in this important indication with high unmet medical need.

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. Recent developments thus aim at shortened desensitization regimens with modified allergens.

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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 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.

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.

Inflammatory: substance evoking inflammation.

Immunostimulatory: substance 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).

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

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

Placebo: dummy medical treatment.

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

This foregoing press release may contain forward-looking statements that include words or phrases such as "evaluate", "expected", "aim", "is thought to", "may", "would", "can/could", "designed", "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 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.