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Cytos Biotechnology initiates combined phase I/IIa study with a novel anti-interleukin-1 beta vaccine in patients with type II diabetes mellitus

Schlieren (Zurich), Switzerland, June 11, 2009 – Cytos Biotechnology Ltd (SIX:CYTN) announced today that it has initiated a combined phase I/IIa clinical study with CYT013-IL1bQb in type II diabetes mellitus. CYT013-IL1bQb is a novel therapeutic vaccine candidate targeting interleukin 1 beta (IL-1 β), an inflammatory cytokine which has been implicated in the pathogenesis of type II diabetes.

The study is a two-stage, randomized, double-blind, placebo-controlled, multicentre study designed to evaluate the safety, tolerability and preliminary efficacy of CYT013-IL1bQb in patients with type II diabetes mellitus. The phase I stage with up to 32 patients will evaluate ascending dose regimens of CYT013-IL1bQb. Thereafter, the following phase IIa stage is planned to include 90 patients and to compare a selected dose regimen of CYT013-IL1bQb to placebo.

About CYT013-IL1bQb

CYT013-IL1bQb is a therapeutic vaccine candidate in development for the treatment of type II diabetes mellitus (also referred to as type II diabetes). It consists of modified IL-1 β molecules coupled to the virus-like particle Qb. IL-1 β is an inflammatory cytokine, which has been implicated in the pathogenesis of type II diabetes through the destruction of pancreatic islet cells that produce insulin¹. The vaccine aims at inducing antibodies against IL-1 β with the goal to decrease inflammation and reduce disease progression. Early clinical studies by independent groups have shown that blockade of IL-1 β with a monoclonal antibody and a receptor antagonist had beneficial treatment effects in type II diabetes patients^{1,2}. The findings suggest that blockade of IL-1 β has potential to modify type II diabetes by preserving insulin producing cells and not just control disease symptoms as common anti-diabetic drugs do. CYT013-IL1bQb represents an active immunization approach expected to induce a long-lasting effect over several months so that convenient dosing schedules and only low amounts of vaccine (in the 100 μ g range per injection) are foreseen for individual patients.

About type II diabetes mellitus

Diabetes mellitus is a group of metabolic disorders that are characterized by chronically elevated blood glucose (sugar) levels caused by a lack of the hormone insulin or by an inability of the body's tissues to respond properly to insulin. Type II diabetes represents the most common form of diabetes (~90% of all cases) and is largely the result of excessive overweight and physical inactivity. The disease has reached epidemic proportions and more than 200 million people worldwide are affected³. The International Diabetes Federation estimated that in 2007, US\$ 232 billion were spent worldwide to treat and prevent diabetes and its complications and that the disease caused 3.8 million deaths worldwide⁴. Traditionally considered a disease of adults, type II diabetes is increasingly diagnosed in children in parallel to rising obesity rates. Health consequences of diabetes can be serious and include kidney failure, diabetic retinopathy, and cardiovascular diseases such as stroke and heart attack. Current medical interventions to control blood glucose levels include increase of physical exercise and improvement of dietary habits, intake of oral anti-diabetic drugs and insulin injections.

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References

1 New England Journal of Medicine, 2007, 356:1517. Interleukin-1-receptor antagonist in type 2 diabetes mellitus.

2 Xoma, Press Release September 8, 2008.

3 International Diabetes Federation (IDF), Diabetes Atlas, 3rd Edition, 2006.

4 International Diabetes Federation (IDF), Diabetes Facts & Figures, www.idf.org, accessed April 2009.

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 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 spin-off from the Swiss Federal Institute of Technology (ETH) in Zurich, the company is located in Schlieren (Zurich). Cytos Biotechnology Ltd is listed on the SIX Swiss Exchange (SIX:CYTN).

Glossary

Antibodies: class of blood proteins generated by the immune system to fight foreign invaders such as bacteria or viruses. Can also be induced against the body's own disease-associated molecules to modulate an ongoing disease process.

Anti-diabetic drugs: drugs that either stimulate insulin secretion, enhance glucose uptake of muscle and fat cells, or increase sensitivity of body cells to insulin. All with the goal to reduce the glucose level in the blood.

Cytokine: small natural protein released by body cells. Can have specific effects on the interactions between cells and on the behaviour of cells.

Dose regimen: describes the dose and the schedule according to which a drug is administered.

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.

Insulin: natural hormone made by pancreatic islet cells. It regulates blood glucose levels.

Monoclonal antibody: antibody derived from a single clone of cells all of which have identical antigen binding sites. Represents an important class of biopharmaceuticals.

Pathogenesis: the development of a disease; includes the origin of the disease and the events leading to that disease.

Phase I/IIa: clinical trial that examines a new drug candidate's safety, tolerability and preliminary efficacy in a small number of patients.

Placebo: dummy medical treatment.

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

Receptor antagonist: refers here to a biopharmaceutical that binds to the interleukin-1 beta receptor and blocks the action of interleukin-1 beta.

Therapeutic vaccine: activates the immune system against disease-associated molecules with the goal of interfering with or modulating an ongoing disease process.

Type II diabetes: most common form of diabetes.

This foregoing press release may contain forward-looking statements that include words or phrases such as "evaluate", "up to", "planned", "will", "aim", "with the goal", "suggest", "potential", "expect", "foreseen", "intend", "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.