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Obesity vaccine enters clinical trial

Immunodrug™ candidate CYT009-GhrQb aims to treat obesity by induction of ghrelin-specific antibodies

Schlieren (Zurich), Switzerland, May 11, 2005 - Cytos Biotechnology AG (SWX:CYTN) announced today that it has initiated a combined phase I/II clinical trial with the Immunodrug™ candidate CYT009-GhrQb, a therapeutic vaccine for the treatment of obesity. The clinical study will include 112 obese individuals with a body mass index (BMI) between 30 and 35, and is designed to evaluate safety, tolerability, and exploratory efficacy of the vaccine.

The multicenter study is being conducted according to a randomized, double-blind and placebo-controlled design. Three different dose regimens of the vaccine will be compared against placebo. The treatment period of six months per individual will be followed by monitoring of safety and efficacy over a further six months. During the treatment, all participants will receive professional counselling to achieve a change in eating habits and improve physical activity. Efficacy of the vaccine will be determined by measurement of body weight. First results of the study are expected in the second half of 2006.

Wolfgang Renner, CEO of Cytos Biotechnology, comments: "Obesity is on its way to become the leading cause of preventable death in western countries such as the United States. Similarly to hypertension and smoking, obesity represents one of the most important risk factors for cardiovascular diseases which account for almost 30% of all global deaths. With the Immunodrugs™ we are developing novel therapeutic vaccines that exactly address these major risk factors. Their mechanism of action is based on the modulation of complex disease mechanisms by antibodies directed to disease-related molecules. CYT009-GhrQb together with our other Immunodrug™ candidates for the treatment of nicotine addiction and hypertension have potential to become convenient and effective treatments for common chronic diseases which have major impact on mortality and well-being in our society."

About obesity

Obesity has become a global pandemic affecting the lives and health of millions of people. According to the World Health Organization, more than 1 billion people worldwide are overweight and of these at least 300 million are clinically obese. Although the underlying causes for obesity are multifaceted, increased consumption of more energy-dense food with high levels of sugar and saturated fats, combined with reduced physical activity have led to obesity rates that have risen three-fold or more in some areas of the world since 1980 (WHO, 2003). Obesity and overweight pose a major risk factor for chronic diseases, including cardiovascular disease, type 2 diabetes, hypertension, stroke, and certain forms of cancer. The modest efficacy of 5-10% weight loss in less than 50% of treated patients and an often unpleasant side effect profile of available pharmacological therapies lead to a small percentage of drug-treated individuals (Nat Rev Drug Discov, 2002, 1:257). More effective surgical intervention on the other hand is very risky and 0.5-1% of patients face death due to complications (Surgery, 2003, 134:613). The cost of obesity in terms of morbidity, mortality and medical expenditure is enormous. 2-7% of total health care costs in developed countries are caused by obesity (WHO, 2003).

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About CYT009-GhrQb

CYT009-GhrQb is a therapeutic vaccine in development for the treatment of obesity. It is designed to instruct the patient's immune system to produce a specific anti-ghrelin antibody response. Ghrelin is a peptide, which has recently been identified as a regulator of eating behaviour. Peripheral administration of ghrelin in humans enhanced both appetite and food intake (J Clin Endocrinol Metab, 2004, 89:2832). In addition, the level of plasma ghrelin in obese individuals is increased after diet induced weight loss and seems to be implicated in the frequently observed rapid regain of weight after diet cessation (Yo-Yo effect). Moreover, the success of gastric bypass surgery in weight control has, at least in part, been attributed to reduced ghrelin levels (N Engl J Med, 2002, 346:1623). These observations suggest that ghrelin may be a key regulator of food intake and body weight in humans. Vaccination with CYT009-GhrQb is anticipated to induce antibodies that bind ghrelin in the circulation and thus inhibit or reduce uptake of ghrelin into the brain, where it exerts its activity. Preclinical experiments in mice have shown that vaccination with CYT009-GhrQb induced high levels of ghrelin-specific antibodies. Furthermore, in mice given a high-fat diet the weight gain was found to be up to 15% lower after vaccination. With CYT009-GhrQb Cytos Biotechnology aims to provide a novel and unique treatment approach for obesity that addresses a high unmet medical need.

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 cytotoxic 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 27 different Immunodrug™ candidates in various disease areas, of which six are in clinical development. The Immunodrug™ candidates are developed both in-house (24) and together with Novartis (1) and Pfizer Animal Health (2). 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 110 employees. Cytos Biotechnology AG has been listed on the SWX Swiss Exchange (SWX:CYTN) since October 2002.

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