Placebo-controlled phase IIa study with hypertension vaccine CYT006-AngQb shows reduction in day-time blood pressure

Schlieren (Zurich), Switzerland, January 26, 2007 - Cytos Biotechnology AG (SWX:CYTN) announced today positive results from a phase IIa study with CYT006-AngQb, a therapeutic vaccine candidate for the treatment of hypertension. The study was a double-blind, placebo-controlled clinical trial conducted with 72 participants with mild to moderate hypertension. It was designed to evaluate safety, tolerability, and exploratory efficacy of two dose levels of the vaccine (100 μg and 300 μg). For efficacy evaluation, the change in blood pressure from baseline to post-treatment was assessed in individual subjects by 24-hour ambulatory blood pressure monitoring.

Treatment with CYT006-AngQb was safe and very well tolerated. The majority of side effects observed were transient and mostly mild local injection site reactions. Mild flu-like symptoms were present in around 10% of the participants and resolved within 1-2 days post-injection. All patients who received the vaccine mounted a strong antibody response against angiotensin II already upon the first injection, which was boosted by the two subsequent injections. The antibody response was long-lived with a half-life of 3-4 months. A significant reduction of the ambulatory day-time blood pressure was observed in the group who received the 300 μg dose of the vaccine (see graph below). As expected, during night-time, when the renin-angiotensin system is less active, differences were smaller and non-significant.

Figure: Mean (SEM) change from baseline of the ambulatory day-time blood pressure is shown. SEM=standard error of the mean; N=number of participants per group.

Dr. Martin Bachmann, CSO of Cytos Biotechnology, commented: “We are very pleased with these study results as they clearly represent a first proof-of-concept for this novel treatment of hypertension. The blood pressure reduction that we have obtained with the 300μg dose is in the
Dr. Wolfgang Renner, CEO of Cytos Biotechnology, added: “With this hypertension vaccine we want to address the one major remaining medical need in this important indication: compliance. Many people apparently don’t like the idea of taking pills every day for the rest of their lives and thus, more than 50% do not take their medications as prescribed. If we could substitute this type of oral therapy with a vaccine that would be given infrequently every few months, we could potentially increase the overall treatment uptake. That in turn could help to reduce the burden of cardiovascular disease in our society.”

**CYT006-AngQb Conference Call and Webcast**

Cytos Biotechnology will host a conference call and Q&A session today, Friday, January 26, 2007 at 10am CET to discuss the study findings.

To access the 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. The presentation slides will be available for download 30 minutes prior to the conference call.

**About hypertension**

Hypertension is a medical condition where the blood pressure is chronically elevated. Although asymptomatic in nature and in itself rarely an acute problem, persistent hypertension is one of the most important preventable causes of premature death worldwide and contributes to around half of all cardiovascular disease (WHO, 2004). It is one of the major risk factors for stroke, heart attack, heart failure, and arterial aneurysm, and is a leading cause of chronic renal failure. Amongst genetic predisposition also several lifestyle habits such as inadequate physical activity, high fat diet, and high salt intake promote high blood pressure. Up to 30% of adults in most countries suffer from hypertension (WHO, 2004). Despite effective and relatively inexpensive treatment available, a health survey in the UK revealed that only 9% of hypertensive people have their blood pressure controlled successfully (National Health Service, UK, 2004). This poor overall treatment success is mainly attributed to the asymptomatic nature of hypertension and the necessity for long-term treatment with medications that require at least once daily dosing.

**About CYT006-AngQb**

CYT006-AngQb is a therapeutic vaccine in development for treatment of hypertension. It is designed to instruct the patient’s immune system to produce a specific anti-angiotensin II antibody response. Angiotensin II is a small peptide in the body and part of the so-called renin-angiotensin system (RAS), an important regulator of blood pressure. Angiotensin II causes blood vessels to narrow, resulting in increased blood pressure. Vaccination with CYT006-AngQb has been shown to induce antibodies that bind angiotensin II. This way, binding to the angiotensin II receptors should be
reduced or prevented and a narrowing of blood vessels no longer occur. The RAS has already been successfully targeted by two major classes of antihypertensive drugs on the market: inhibitors of the angiotensin-converting-enzyme (ACE) and antagonists of the angiotensin II type I receptor. Like other antihypertensive drugs these also come with the need for daily dosing and don't provide a solution for improving patient compliance. Treatment with CYT006-AngQb should allow for convenient dosing schedules and smooth control of blood pressure due to a sustained antibody response induced by vaccination.

About the phase IIa study
This study was a randomized, double-blind and placebo-controlled study conducted in two clinical centres in Germany. It included 72 healthy male and female participants aged 18-65 with mild to moderate hypertension (systolic blood pressure between 140–179mmHg; diastolic blood pressure between 90-109mmHg). It was a staggered, ascending dose study that evaluated two dose levels of the vaccine (100 μg and 300 μg). Each of the two dose groups included 36 participants who were randomized to CYT006-AngQb (n=24) or placebo (n=12) and received 3 subcutaneous injections at week 0, 4 and 12. The third injection was given only on the condition that individual antibody levels were declining after a peak around week six. This safety condition was fulfilled in all cases. For highest immunogenicity of Immunodrugs™, however, a compressed regimen appears more favorable and will be tested in future studies. The effect of the treatment on systolic and diastolic blood pressure was assessed by 24-hour ambulatory blood pressure monitoring at baseline and post-treatment (i.e. 2 weeks after the last injection). Day-time ambulatory blood pressure was determined as the average of measurements done every 15 minutes between 6am and 10pm, whereas night-time ambulatory blood pressure was determined as the average of measurement done every 30 minutes between 10pm and 6am. Blood pressure was measured with the Ultralight ABD Monitor 90217 (Spacelabs Medical).

This phase IIa study was part of a combined Phase I/IIa study and initiated after positive preclinical and phase I clinical data were obtained, which were published in the Journal of Hypertension in January 2007.

About the analysis
Out of 72 enrolled participants, 67 patients finalized the treatment up to 4 months and could be included into the analysis. For the analysis, the placebo groups of the two dose groups were pooled (total n=24). For statistical analysis, ANCOVA (analysis of covariance) was used to compare vaccine-induced changes in ambulatory blood pressure from baseline within each dose group.

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About Cytos Biotechnology

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 full 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 Pharma 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

Angiotensin II: a molecule of the RAS inducing vasoconstriction of blood vessels and other effects to raise blood pressure.

Antibody: class of blood proteins generated by the immune system to bind and neutralize foreign materials such as bacteria or viruses. Can also be directed against the body’s own disease-associated molecules.

Antihypertensive drugs: a class of drugs used for treatment of high blood pressure.

Asymptomatic: without symptoms.

Compliance: a patient’s adherence to a recommended course of treatment.

Diastolic blood pressure: the lowest pressure within the arterial blood stream occurring during each heart beat. The term “diastolic” is used to refer to the relaxation of the heart between muscle contractions.

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.

mmHg: blood pressure values are universally stated in millimetres of mercury (mmHg).

Immunogenicity: the ability of a substance to evoke an immune response.

Peptide: a fragment of a protein comprised of two or more amino acids.

Phase IIA: a clinical trial that examines a new drug candidate’s safety and exploratory efficacy and may involve between 10 and 100 patients.


RAS: renin-angiotensin system. A hormone system that regulates long-term blood pressure and blood volume in the body.

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

Receptor: a protein molecule that binds and responds to a certain interaction partner such as hormones, immune mediators or other substances.

Subcutaneous: under the skin.

Systolic blood pressure: the highest pressure within the arterial blood stream occurring during each heart beat. “Systolic” refers to the contraction of the heart muscle.

Therapeutic vaccine: a preparation of disease-related molecules (antigens) of foreign or self origin that is capable of activating the immune system against such antigens with the goal to modulate disease processes.

This foregoing press release may contain forward-looking statements that include words or phrases such as “designed”, “expect”, “will”, “could”, “would”, “potentially”, “should”, “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 AG.