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## Interim analysis of an ongoing phase II study with nicotine vaccine shows primary endpoint not achieved

Schlieren (Zurich), Switzerland, October 15, 2009 – Cytos Biotechnology Ltd (SIX:CYTN) was informed today by Novartis that an interim analysis of a Phase II study with the nicotine vaccine NIC002 showed that the primary endpoint was not achieved. This endpoint was defined as a statistically significant difference in continuous abstinence from smoking determined from weeks 8 to 12 after start of treatment compared to placebo. The study, which is ongoing, is a double blind, placebo-controlled, multi-centre study to evaluate the efficacy, safety, tolerability and immunogenicity of repeated administrations of 100µg NIC002 in 200 cigarette smokers who are motivated to quit smoking. In this study the treatment was safe and well tolerated but failed to induce sufficiently high antibody titers, which may have led to the negative outcome. Novartis is continuing the study in order to collect more long-term data on the efficacy and safety of NIC002 and will decide on the next steps once the scheduled 12 month duration of the clinical trial is completed and when all data have been analyzed.

### **About NIC002**

NIC002 is a therapeutic vaccine in development for the treatment of nicotine addiction. Vaccination with NIC002 has been shown to induce nicotine-specific antibodies that bind nicotine in the bloodstream. As the complex of nicotine attached to an antibody is too large to cross the blood-brain barrier, nicotine uptake into the brain and the subsequent stimulation of nicotine-responsive nerve cells is believed to be reduced. In this way, the reward-inducing and addiction-driving stimulus of nicotine should be minimized and abstinence from smoking more easily achieved and maintained. In a previous Cytos phase II clinical trial the vaccine has promoted and sustained long-term abstinence from smoking in the subgroup of smokers that achieved high antibody levels upon vaccination.

### **About nicotine addiction**

Worldwide, there are 1.3 billion smokers and with 4.9 million tobacco-related deaths per year, tobacco use is the leading cause of preventable death in the world today (WHO; Facts about smoking and health, 2006). Smoking harms nearly every organ of the body, resulting in life-threatening diseases like cancer, chronic obstructive pulmonary disease (COPD), stroke, and circulation disease. Nicotine is a plant-derived alkaloid and the principal addictive component of tobacco. Upon inhalation of cigarette smoke, nicotine passes into the bloodstream and, within seconds, crosses the blood-brain barrier to enter the brain where it stimulates specific nerve cells. Stimulation of these nerve cells leads to the release of messenger molecules, which give rise to an almost immediate reward and feeling of pleasure. This sensory stimulus is critical to the addictive properties of nicotine and causes a high relapse rate after quitting attempts. Although nearly 75% of smokers in the U.S. report that they want to stop smoking, less than 5% of those who make an attempt are able to stay tobacco-free for 3 to 12 months (CDC, USA; Surgeon General's Report, 2004).

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**Glossary**

**Antibody:** class of blood proteins generated by the immune system to neutralize foreign material such as bacteria, viruses or toxins (i.e. antigens).

**Blood-brain barrier:** the blood-brain barrier is a physical barrier between the blood vessels in the central nervous system, and the central nervous system itself. The barrier stops many substances from traveling across it.

**Double blind:** a design commonly applied in clinical trials where neither the doctor nor the patient knows whether placebo or the active drug is being administered.

**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.

**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 86 full-time employees. Cytos Biotechnology Ltd is listed on the SIX Swiss Exchange (SIX:CYTN).*

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