

Clinical trial advances Cytos Biotechnology's second Immunodrug™ platform

Good safety, tolerability and strong T-cell immunogenicity of QbG10 demonstrated in healthy volunteers. Immunodrug™ programs based on QbG10 in allergy desensitization and in tumor therapy are on track.

Schlieren (Zurich), Switzerland, September 16, 2004 - Cytos Biotechnology AG (SWX:CYTN) announces today that it has successfully completed a clinical phase I study with its novel Immunodrug™ carrier QbG10. This phase I study was designed to evaluate safety, tolerability and T-cell immunogenicity of QbG10 in 35 healthy volunteers. The investigational agent CYT003-QbG10 consists of the virus-like particle Qb packaged with an immunostimulatory DNA sequence called G10. The clinical trial, which was conducted as a single-center, randomized and placebo controlled study, compared different doses and formulations of QbG10 in five study groups with seven volunteers in each group. Six of the seven volunteers in each group received QbG10 and one volunteer received placebo.

In this study, QbG10 was safe, well tolerated, and highly immunogenic. As expected from previous trials with Qb, all participants who received QbG10 mounted high levels of Qb-specific antibodies, whereas participants receiving placebo showed no Qb-specific antibody responses. 31 of the 35 participant samples could be analysed for T-cell activity, four had to be excluded due to poor blood sample quality after shipment. All of the analysed participants (11 / 11) in the study groups receiving QbG10 in Alum responded with a specific T-cell response as measured by interferon gamma release, an "anti-allergic" cytokine. Qb-specific T-cells were detected in frequencies of up to 0.1% (of all T-cells), a range that is normally seen in natural viral infections. In the three study groups receiving QbG10 without Alum, 73% (11 / 15) responded with a specific T-cell response, whereas none of the five placebo treated participants was positive.

QbG10 was very well tolerated; adverse events were mostly local injection site reactions such as pain, reddening and swelling. These symptoms disappeared within one to three days and were graded as mild (98%) or moderate (2%).

Wolfgang Renner, CEO of Cytos, comments: "We are very pleased as the obtained data confirm our expectations that QbG10 is indeed capable of inducing strong T-cell responses in humans. This positive outcome in the clinic clearly advances our second Immunodrug™ platform which has applications in various diseases. We will now move towards a phase II efficacy study in allergy, which is planned to start in Q4 2004. A combined phase I/II clinical trial to treat malignant melanoma is projected to start in the second half of 2005."

About the novel Immunodrug™ carrier QbG10

QbG10 consists of the virus-like particle Qb, packaged with a special immunostimulatory DNA sequence called G10. As shown in this clinical phase I trial as well as in preclinical models, QbG10 can induce a so-called Th1 type immune response; a situation which is believed to promote allergy

desensitization. For this indication, QbG10 will thus be added as an adjuvant to the natural allergen extract. For application in tumor therapy, specific proteins or peptides that are produced predominantly by cancer cells are coupled to the Immunodrug™ carrier. In preclinical experiments linkage of such a peptide specifically directed the killer cell response against the cancer cells, which successfully eradicated established tumors in mice.

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. Immunodrug™ candidates 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 23 different Immunodrug™ candidates in various disease areas, which are developed both in-house and together with Novartis. 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 109 employees. Cytos Biotechnology AG has been listed on the SWX Swiss Exchange (SWX:CYTN) since October 2002.

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