



Neovacs' preliminary clinical trial results (presented at the GASTRO conference) are supportive of the safety, immunogenicity and therapeutic effect of the company's Kinoid approach; clinical testing is to be expanded

Paris, November 26, 2009 -- Neovacs, a biotechnology company developing proprietary immunotherapeutics for autoimmune and chronic diseases, today released a summary of the presentation made by Chief Medical Officer Pierre Vandepapeliere at the GASTRO 2009 conference in London, UK. The presentation featured preliminary data from the ongoing Phase I/II clinical trial of Neovacs' TNF α Kinoid active immunotherapy in Crohn's Disease patients.

The Phase I/II study is testing three different dose levels of the Kinoid in patients with moderate to severe Crohn's Disease. Thirteen patients out of a planned total of 21 have been recruited to date. The study's primary objective is to assess the Kinoid's safety and its ability to induce an immune response to tumor necrosis factor alpha (TNF α). A secondary objective is to look at the therapeutic effect as measured by the clinical disease score and markers of disease activity.

The study's preliminary findings are as follows:

- The Kinoid treatment's safety profile has been excellent to date. There have been no serious adverse events, unexpected infections or premature study withdrawals. All the local and systemic reactions to Kinoid administration have been mild, transient and limited to a few patients. The patients' immune systems respond normally to immune competence tests.
- TNF α Kinoid treatment induces the production of antibodies against TNF α . This response is transient but can be boosted by an additional administration at six months. This recall response is also transient. Administration of the Kinoid does not, however, produce a cellular immune response against TNF α .
- The data related to a potential therapeutic effect are encouraging, given that the study was not designed to demonstrate efficacy. Twelve weeks into therapy, most patients showed a clinical response and over half were in clinical remission, as measured by the Crohn's Disease Activity Index. In all patients tested, decreases in levels of calprotectin (a protein associated with intestinal inflammation) are also suggestive of a therapeutic effect. These indications of a clinical response will need to be confirmed in controlled, blinded studies.

Neovacs' TNF α Kinoid is in clinical development for the treatment of TNF α -mediated autoimmune and chronic diseases. Later this year, Neovacs expects to initiate a double-blind, placebo-controlled Phase II study of TNF α Kinoid in rheumatoid arthritis patients who no longer respond to a TNF α inhibitor because of the development of anti-drug antibodies. This study (to be performed in partnership with the diagnostics company BMD) will be part-financed by significant funding from OSEO/ISI, the French state innovation agency. A Phase II study of TNF α Kinoid in Crohn's disease patients is also planned for 2010. In the first quarter of 2010, Neovacs also expects to initiate a Phase I/II study of its second product candidate (an interferon alpha Kinoid) in patients with systemic lupus erythematosus.

About Neovacs

Neovacs is a biotechnology company focused on an active immunotherapy technology platform with applications in autoimmune diseases and other chronic conditions. It was founded as a spin-off from Pierre & Marie Curie University in Paris by Professor Daniel Zagury, MD, one of the world's leading immunologists. The key investors are Truffle Capital, Novartis Venture Fund and OTC Asset Management.

The company's lead program (an immunotherapy targeting TNF α -mediated autoimmune diseases) is currently in a Phase I/II study in subjects with Crohn's disease. This product candidate is also the focus of a collaboration with the diagnostics company BMD, with the objective of developing theranostic tools for personalized care.

Neovacs' near-term milestones include the expansion of the lead clinical program (TNF α Kinoid) into new indications (Q4 2009) and the initiation of clinical trials of a second product - an immunotherapy targeting interferon alpha (IFN α) in lupus disease (Q1 2010). The company's R&D has also generated a broad patent estate.

Disclaimer: drug development is an inherently uncertain and unpredictable process. Neovacs' statements regarding the future depend on research that has yet to be performed and on a number of other factors. As a consequence, the company's future performance and financial results may differ significantly from those currently forecast.

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