



Neovacs to expand clinical testing of its TNF- α Kinoid lead product candidate following positive preliminary findings from a Phase I/II study

Paris, June 22nd, 2009 -- Neovacs, a biotechnology company developing proprietary immunotherapeutics for autoimmune and chronic diseases, today announced that subject to regulatory consent, it plans to initiate a Phase II study of its TNF- α Kinoid later this year in rheumatoid arthritis patients who have failed treatment with at least one TNF- α inhibitor. The decision to proceed with the trial was based on an initial review of encouraging data from the company's Phase I/II study in Crohn's disease.

The proposed trial will initially test two dose levels of the TNF-Kinoid, with the option of expanding recruitment and extending follow-up in one dose group on the basis of serological and clinical responses. The multicentre, Europe-wide trial received significant public funding from OSEO, the French state innovation agency.

"We are highly encouraged by the safety data and preliminary indications of efficacy that are emerging from our Crohn's disease study," commented Neovacs CEO Guy-Charles Fanneau de La Horie. "With all the initial dose groups having received the Kinoid, we have not seen any significant adverse reactions; importantly, it is very clear that the Kinoid does not induce cell-mediated immunity. Furthermore, all the patients in the higher dose groups treated to date have mounted an antibody response and are in clinical remission. It makes sense to take a further step forward by testing the Kinoid in a Phase II rheumatoid arthritis trial. We are grateful for the public funding that is enabling us to expand our clinical efforts without delay", added Mr de la Horie.

The ongoing Phase I/II dose-escalation study (taking place in South Africa and Switzerland) is recruiting between 12 and 18 patients with active Crohn's Disease and is intended to evaluate the Kinoid's safety and immunogenicity. In the context of active immunotherapy, safety parameters include (i) the absence of adverse reactions and (ii) serological measurements of the nature of the immune response, such as the kinetics of the antibody response and whether the cellular immune system (and specifically T cell memory) is stimulated. The trial is also tracking a clinical endpoint for disease status - the Crohn's Disease Activity Index.

About TNF α -dependent autoimmune diseases

These diseases affect the bones and joints (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, etc.), the digestive tract (Crohn's disease and hemorrhagic rectocolitis) and the skin (psoriasis). In seven major developed countries alone (USA, Japan, the UK, Germany, France, Italy and Spain), there are 9.3 million people with bone and joint diseases, 2.1 million with digestive diseases and 16.5 million with psoriasis (Datamonitor, 2007).

About Neovacs

The biotechnology company Neovacs is focused on an active immunotherapy technology platform with applications in autoimmune disease 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 company's lead program (an immunotherapy targeting certain inflammatory 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.

Néovacs' near-term milestones include clinical proof of concept for its lead product (mid-2009), the expansion of the lead clinical program into new indications (H2 2009) and the initiation of clinical trials of a second product - an immunotherapy targeting Lupus disease (H2 2009). 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.

Press contacts

Alize RP

Caroline Carmagnol
+33 (0) 6 64 18 99 59
caroline@alizerp.com

Juliette Vandenbroucque

+ 33 (0) 1 41 22 07 32
juliette@alizerp.com

Neovacs

contact@neovacs.com