



## **Neovacs initiates a Phase II clinical trial of TNF $\alpha$ Kinoid in rheumatoid arthritis patients failing TNF $\alpha$ monoclonal antibody therapy**

**Paris, December 8, 2009** -- Neovacs, a biotechnology company developing proprietary immunotherapies for autoimmune and chronic diseases, today announced the initiation of a Phase IIa clinical study of its TNF $\alpha$  Kinoid immunotherapy in rheumatoid arthritis patients who have ceased to respond to an anti-TNF $\alpha$  monoclonal antibody and who test positive for anti-drug antibodies (ADAs). The announcement follows trial clearance by the French regulatory authority (AFFSAPS) and the central ethics committee. Neovacs has also submitted the trial protocol to the relevant authorities in two other European countries and has already received regulatory clearance in one and ethics committee approval in the other.

*"This is a major milestone and an excellent way to end 2009 – a year that has seen Neovacs make significant progress", stated Guy-Charles Fanneau de la Horie, CEO of Neovacs, "Along with the ongoing Phase Ib trial in Crohn's patients, this new Phase IIa trial adds a second indication for our TNF-Kinoid. We also plan to initiate clinical testing of our second product, IFN $\alpha$  Kinoid, in early 2010".*

The Phase IIa study, to be performed in collaboration with the diagnostics company BMD, is part-financed by significant funding from OSEO/ISI, the French state innovation agency. The double-blind, placebo-controlled trial will recruit up to 48 patients in three European countries. The primary objective is to select the dose levels and a dosing schedule to be tested in a subsequent Phase IIb study. The treatment's safety and clinical efficacy will be secondary endpoints.

*"Anti-TNF monoclonals are very effective, but often lose their efficacy over time. ADAs are a major factor in this therapeutic failure", commented Professor Marie-Christophe Boissier, Head of the Rheumatology Department at Avicenne Hospital, Bobigny, France, and the study's coordinating investigator for France "Active immunotherapy with Neovacs' TNF $\alpha$  Kinoid may be of significant value in a patient population that currently has limited effective treatment options".*

### **About TNF $\alpha$ -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**

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, TNF $\alpha$  Kinoid, an immunotherapy targeting TNF $\alpha$ -mediated autoimmune diseases, is currently in Phase I/II clinical trials in Crohn's disease patients. This product candidate is also the focus of a collaboration with the diagnostics company BMD, with the goal of developing theranostic tools for personalized care.

The company expects to initiate clinical trials of a second product candidate, IFN $\alpha$  Kinoid, an immunotherapy targeting interferon alpha (IFN $\alpha$ ), in lupus patients in the first quarter of 2010.

The company's R&D has 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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