



## **A new milestone achieved with IFN $\alpha$ -Kinoid in the phase I/II study in Lupus patients**

**Paris, September 27, 2010 - Neovacs (Alternext Paris: ALNEV), a biotech company focused on an active immunotherapy technology platform (Kinoids™) with applications in the treatment of autoimmune diseases, inflammatory diseases and cancer has received DSMB authorization to proceed to the next dose level in its ongoing phase I/II trial in lupus.**

Administration of the second dose level in patients recruited in July was completed as expected. Having reviewed the data related to these patients on September 24, the Data and Safety Monitoring Board, an independent committee which is responsible for overseeing the conduct of the study and in particular for patient safety, authorized Neovacs to proceed to the next higher dose of IFN $\alpha$ -Kinoid. Neovacs is now recruiting patients for this dose group.

*"We are making rapid progress in our phase I/II trial with our IFN $\alpha$ -Kinoid drug candidate to treat patients suffering from the lupus disease. The DSMB's decision confirms the good tolerability of IFN $\alpha$ -Kinoid to date, which has now been administered to patients at two dose levels. We are encouraged by our good progress and our objective of recruiting up to 28 patients should be achieved quickly."* commented Pierre Vandepapelière, MD, PhD in biomedical medicine and Neovacs' Chief Medical Officer.

Preliminary results of the study are expected during the first half of 2011. The study is placebo-controlled, double-blind with dose-escalation and randomisation at each dose level. Patients must present symptoms of moderate disease and the primary objective of the ongoing study is to gather data on the tolerability and safety of IFN $\alpha$ -Kinoid. Secondary objectives include analysis of the immune response and measurements of disease activity and IFN $\alpha$  markers.

### **About lupus**

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body leading to widespread inflammation and tissue damage. Prevalence estimates vary widely, and range as high as 1.5 million in North America (the Lupus Foundation of America) and 5 million worldwide. The Centers for Disease Control estimates a 2005 prevalence of 322,000 with definite or probable SLE in the US. Lupus disease may first occur at any age, though peak diagnosis is between the ages of 15 and 40. It is far more common in women than men. People with SLE may experience fatigue, pain or swelling in joints, skin rashes, and fevers. It can also affect the lungs, kidneys, and blood vessels. There has been no new treatment approved for lupus for over fifty years. Scientists have highlighted the overproduction of the interferon alpha cytokine as a key factor in the causation and development of the disease.

## **About Neovacs**

Neovacs is a biotechnology company focused on an active immunotherapy technology platform (Kinoids™) with applications in autoimmune diseases and other chronic conditions. Neovacs' current portfolio consists of 3 drug candidates: TNF-Kinoid, IFN $\alpha$ -Kinoid and VEGF-Kinoid. The company's lead immunotherapy program (TNF-Kinoid) targets TNF-mediated chronic inflammatory diseases. For TNF-Kinoid, a Phase I/II clinical trial in Crohn's disease and a Phase II trial in rheumatoid arthritis (RA) are ongoing. The latter clinical study is also the focus of collaboration with the French diagnostics company BMD, with the goal of developing theranostic tools for personalized care in RA. Patient recruitment is ongoing in a Phase I/II trial of Neovacs' second product candidate (IFN $\alpha$  -Kinoid, an immunotherapy targeting interferon alpha) in the treatment of lupus. Neovacs' R&D has generated a broad patent estate.

**For more information, visit the Neovacs web site at [www.neovacs.com](http://www.neovacs.com)**

## **Contacts**

### **Presse - Alize RP**

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

### **Neovacs**

Florence Hocdée - Leroy  
+33 (0) 1 53 10 93 14  
[fhocdeeleroy@neovacs.com](mailto:fhocdeeleroy@neovacs.com)

### **Investors – Actifin**

Nicolas Meunier  
+ 33 (0) 1 56 88 11 11  
[nmeunier@actifin.fr](mailto:nmeunier@actifin.fr)