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## Phase IIa clinical study of TNF-Kinoid in rheumatoid arthritis fully enrolled

Initial results expected during fall 2011

**Paris, 3<sup>rd</sup> August 2011 - 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, today announced that its TFN-K-003 clinical study has recruited all patients called for by the study protocol and consistent with the Company's development plan. Initial results should be announced during the fall and final results by the end of 2011.**

The TFN-K-003 study of Neovacs' TFN-Kinoid is a double-blind, placebo-controlled trial in Rheumatoid Arthritis (RA) patients who have developed a secondary resistance to TNF-inhibitors. It was initiated in March 2010, with patients recruited in France, Argentina, Belgium, Bulgaria, Chile, Croatia and Romania.

**The primary objective of the study is to select, based on the anti-TNF $\alpha$  immune responses, the dose levels and dosing schedule to be tested in a subsequent Phase IIb study. 3 doses (90, 180 and 360 mcg) and 2 dosing schedules are being tested. The treatment's safety and clinical efficacy are secondary endpoints.**

Initial results relating to the first two dose (90 and 180 mcg) cohorts should be released during fall 2011 and the final results by end 2011.

This Phase IIa study is being conducted in partnership with bmd, a French diagnostics company, and partly financed by Oséo, the French State innovation agency, up to a maximum of €7.5 million of which €6.4 million is intended for Neovacs. The aim of the Tracker project is to develop a holistic therapeutic strategy for patients with rheumatoid arthritis who have developed a secondary resistance to TNF-inhibitors.

*"We are very happy to reach this milestone. This is the first study with TNF-K in RA, in patients who, having developed a secondary resistance to TNF-inhibitors, have limited therapeutic options. We will have very interesting data to present on both our candidate-drugs in the coming months."* commented Guy-Charles Fanneau de La Horie, CEO of Neovacs.

The market for TNF inhibitors was valued at over 20 billion US\$ in 2010 and is still growing. However, these products frequently lose efficacy over time, often quite rapidly. According to Datamonitor, by 2012, the number of RA patients having failed at least one TNF inhibitor will exceed the number taking their first, emphasizing the strong need for new treatments. TNF-K induces the production of human polyclonal antibodies which should not generate resistance from the patient's immune system and may also better neutralize TNF $\alpha$ .

### About TNF $\alpha$ -mediated disease

TNF $\alpha$ -mediated diseases affect the bones and joints (RA, ankylosing arthritis, psoriatic arthritis, etc .) the digestive tract (Crohn's Disease, ulcerative colitis) and the skin (psoriasis). In the seven major developed countries alone (USA, Japan, Germany, France, UK, 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.

## **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 2 drug candidates in clinical studies: TNF-Kinoid and IFN $\alpha$ -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 has been completed and 2 Phase II trials in rheumatoid arthritis and Crohn's Disease are ongoing. Neovacs' second product candidate (IFN $\alpha$  -Kinoid, an immunotherapy targeting interferon alpha) is in a Phase I/II study in lupus patients. Preliminary data have recently been announced, showing a strong immunogenicity, good tolerance and a promising pharmacodynamic activity. Final results will be communicated in September 2011. Neovacs' R&D has generated a broad patent estate. Neovacs recently raised more than 10 million € in new capital.

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

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