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# NEOVACS SUCCESFULLY ENROLLS FIRST PATIENTS IN ITS PHASE IIB STUDY OF TNF-KINOID FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

Paris, December 9, 2013 – NEOVACS (Alternext Paris: ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, announced today that it has successfully enrolled the first patients in the Phase IIb study of TNF-Kinoid for the treatment of rheumatoid arthritis (RA). These patients have received a first injection of the Kinoid.

The TNF-Kinoid's development plan is in line with the schedule announced by the Company at the time of its capital increase in March 2013. Proceeds from the capital increase are financing the study.

Neovacs has received consents from the regulatory authorities and ethics committees in Belgium, Moldova, Georgia, Hungary, Czech Republic, Poland and Lebanon. Further approvals will be obtained soon in the other countries of the study.

« These first inclusions within scheduled timelines are a major milestone in Neovacs' development. The study has been rapidly and unevently approved in many sites across numerous countries, outlining the need for novel therapeutic strategies and the interest raised by Neovacs kinoid. Over 15 study centers are now operational, and dozens of patients have been screened for enrollement. The majority of the remaining centers should open before the end of the year, allowing us to rapidly enroll more patients and finalize the recruitment on schedule » comments Pierre Vandepapelière, Chief Medical Officer of Neovacs.

"There remains a need for new therapies for chronic inflammatory diseases. Targeting TNF $\alpha$ , a validated and well-understood cytokine, via a polyclonal immune response is a promising therapeutic strategy » states Professor Patrick Durez of Cliniques Universitaires Saint-Luc academic hospital of the University Catholique de Louvain (UCL) in Brussels, expert in the treatment of RA and principal investigator of the study.

# The TNF-Kinoid phase IIb clinical study in Rheumatoid Arthritis

The international, double-blind, randomized, placebo-controlled TNF-K-006 study will recruit 140 patients with active disease despite methotrexate. The primary endpoint for the study is clinical efficacy. Results are expected Q4 2014.

<sup>&</sup>lt;sup>1</sup> Patients are being screened in order to insure that they meet inclusion criteria for participating in the clinical study. Patients must notably show no trace of residual monoclonal antibodies.

Promising results of a phase IIa study of TNF-Kinoid in RA have been published in early 2012. The study had demonstrated the excellent safety profile of the Kinoid and had shown encouraging efficacy results in patients who had developed anti-TNF antibodies after injection with the Kinoid.

"The recruitment of the first patient is an excellent news. Our clinical program is now moving full speed ahead, and we are looking forward to the results. We are confident that they will demonstrate the clinical efficacy of our immunotherapy for the treatment of rheumatoid arthritis. Anti-TNF therapies are one of the largest, and growing, markets in the pharmaceutical industry, yet the therapeutic response they induce is not fully satisfying » concludes Miguel Sieler, CEO of Neovacs.

### The market of anti-TNF

The market for anti-TNF therapies is estimated at over 27 billion dollars in 2012<sup>2</sup>. The top selling drug in this market totaled sales of 9.3 billion dollars in 2012, a 29% increase from 2011<sup>3</sup>.

## The Neovacs approach in the treatment of auto-immunes and inflammatory diseases

Neovacs' innovative therapeutic approach, the Kinoid technology, stimulates the patient's immune system to generate antibodies that target a specific deregulated protein (cytokine) involved in the development of his/her disease. The Kinoid induces self polyclonal antibodies which bind multiple epitopes, making them more likely to be effective in neutralizing the targeted cytokine. Neovacs is developing two active immunotherapies based on Kinoid technology: TNF-Kinoid and IFN $\alpha$ -Kinoid. Both products have featured extensively in prestigious scientific meetings and journals over the last few years.

### **About Neovacs**

Neovacs is a biotechnology company focused on an active immunotherapy technology platform (Kinoids) with applications in autoimmune and/or inflammatory diseases. On the basis of the company's proprietary technology for inducing a polyclonal immune response (covered by five patent families that run until at least 2023) Neovacs is focusing its development efforts on two active immunotherapies: TNF-Kinoid is being developed for the treatment of TNF-mediated autoimmune diseases such as rheumatoid arthritis and Crohn's disease, whereas IFN $\alpha$ -Kinoid is being developed for the indication of lupus. The goal of the Kinoid approach is to enable patients to have access to safe treatments with efficacy that is sustained in these life-long diseases.

### For more information on Neovacs, visit www.neovacs.fr

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<sup>&</sup>lt;sup>2</sup> Pharmaceutical company data, 2012

<sup>&</sup>lt;sup>3</sup> Abbvie, Annual report 2012