



Press Release

Neovacs successfully enrolls first patient in its Phase II clinical study of TNF α -Kinoid[®] in rheumatoid arthritis

Paris, March 29, 2010 - Neovacs, a biotechnology company developing proprietary immunotherapies for autoimmune and chronic diseases, today announced it has initiated, in France, treatment of the first patient in a Phase II clinical trial to evaluate the TNF α -Kinoid[®] (TNF-K) in rheumatoid arthritis patients who have failed treatment with an anti-TNF α monoclonal antibody because of the development of resistance to monoclonal antibodies.

This trial is the initial clinical work package in the TRACKER program¹, for which Neovacs and Biomedical Diagnostics (bmd), an *in vitro* diagnostics company specializing in auto-immune disease, obtained, in 2008, a €7.9 million grant (including €6.4 million for Neovacs, as project leader) from the French state innovation agency Oséo ISI.

About the Phase II clinical trial of TNF α -Kinoid[®] in rheumatoid arthritis patients

This randomized, double-blind, placebo-controlled Phase II study is being conducted in 3 countries: France, Belgium and Switzerland. All the necessary regulatory authorizations have been received, and the trial will enroll up to 48 patients. The primary objective is to select the dose levels and dosing schedule to be tested in a subsequent Phase IIb/III study. The treatment's safety and clinical efficacy are secondary endpoints. The trial results are expected in mid-2011 and will be followed by a Phase IIb/III trial.

Neovacs' TNF-K has featured extensively in the most prestigious scientific meetings and journals over the last few years: *Arthritis Research & Therapy* (2009), the *Proceedings of the National Academy of Sciences* (2006) and the 2009 GASTRO conference in London. At the end of 2008, TNF-K was selected by Thomson Reuters as the most promising drug to be entering Phase II clinical trials.

¹ The aim of the Tracker theranostics programme (co-developed by Neovacs and BMD) is to elaborate a comprehensive patient management strategy in rheumatoid arthritis by validating BMD's assay for neutralizing antibodies and testing a therapeutic solution based on Neovacs' anti-TNF active immunization approach.

Professor Marie-Christophe Boissier, Head of the Rheumatology Department at Avicenne Hospital in Bobigny (France) and Director of the "Physiopathology and biotherapies of Rheumatoid Arthritis" laboratory of Paris 13 University commented: *"This first administration of TNF-K in a RA patient is a very important and promising step, especially when viewed against a worrying context of resistance to anti-TNF monoclonal antibody-based rheumatoid arthritis therapies. The active anti-TNF immunization approach using NEOVACS' kinoid may provide an effective solution for the many patients suffering from this very disabling disease"*.

"The recruitment of the first patient into this Phase II study of TNF-K is a crucial milestone in our drug candidate development program in rheumatoid arthritis - a market that was estimated to be worth over \$7 billion in 2007", emphasized Neovac CEO Guy-Charles Fanneau de La Horie.

Neovacs has conducted several pre-clinical trials in rheumatoid arthritis models and, since 2008, a Phase I/II study (to be completed in 2010) in Crohn's disease. The initial very promising results from this study were presented at GASTRO 2009 in London. In 2010, Neovacs plans to launch two additional trials:

- A Phase IIa study with TNF-K in Crohn's disease ;
- A Phase I/II study with a second product, IFN-K, in Lupus. This trial has received regulatory clearance in Belgium, with other clearances expected soon and should start within the next few weeks.

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 rheumatoid arthritis

Rheumatoid arthritis (RA) is an auto-immune, inflammatory disease in which the immune system attacks the synovial membrane and/or the joint capsule. At first, the inflammatory response leads to progressive destruction of the joint's muscles, tendons and ligaments. This produces pain, swelling, severe, progressive joint deformation and functional impairment leading to mobility and dexterity problems.

The statistics on RA are worrying: 5 years after diagnosis of the disease, 29% of the patients in work will have been obliged to stop. This figure rises to 31.5% after 10 years. In addition to these specific symptoms, RA is associated with reduced life expectancy, with (for example) a higher incidence of certain types of cancers (such as lymphoma) in RA patients. Hence, a 50-year-old woman suffering from RA can expect to lose 4 years of life, compared with an RA-free woman of the same age.

Rheumatoid arthritis is often graded according to the disease severity. It is estimated that 50% of RA patients have a mild (and often undiagnosed) form, 30% suffer from moderate disease and 20% have severe disease. The prevalence of RA is estimated at between 0.3% and 1% of the general population. Even though RA can affect all ages (including children), around 70% of RA patients are women. Disease onset generally occurs between the ages of 30 and 50.

On March 19th, Neovacs announced its planned initial public offering on the Alternext Exchange of NYSE Euronext Paris, after getting, on March 18th, the approval from the Autorité des Marchés Financiers (AMF, the French stock market regulator) on its Prospectus (reference number 10-055).

About Neovacs

The biotech company Neovacs aims at becoming a major player in the treatment of autoimmune disease, inflammatory disease and cancer. It was founded as a spin-off from Pierre & Marie Curie University in Paris. The company is a leader in the field of active immunotherapy against human cytokines, thanks to a new approach based on therapeutics called Kinoids®. Neovacs' portfolio currently consists of drug 3 candidates: TNF α -K, IFN α -K and VEGF-K.

The most advanced candidate (TNF-K) is an immunotherapy which targets a number of inflammatory diseases involving TNF α . It is moving into Phase II clinical trials in rheumatoid arthritis and is also scheduled to enter Phase II in Crohn's disease in the middle of 2010. This drug candidate is also the focus of a collaboration with the diagnostics company bmd, with the goal of developing theranostic tools for personalized care in patients who developed an antibody-mediated resistance to today's existing treatments (monoclonal antibodies). This program is receiving financial support from Oséo ISI, the French state innovation agency.

In the first half of 2010, the company is also set to initiate first-in man clinical trials for its second candidate product, IFN α -K - an immunotherapy which targets interferon alpha (IFN α) and has an indication in lupus.

The company's R&D efforts have generated a broad patent estate, providing excellent protection of its technology platform and the derived Kinoid® therapeutics. Neovacs' main investors are Truffle Capital, Novartis Venture Fund and OTC Asset Management. For more information, visit the Neovacs web site at www.neovacs.com.

Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the prospectus filed with the AMF, which is available on the AMF website (<http://www.amf-france.org>) or on Neovacs' website (www.neovacs.com).

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