



Neovacs initiates a Phase II clinical study of its TNF-Kinoid in Crohn's Disease Patients

Paris, 10 January 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 the start of a Phase 2 international clinical trial to study the efficacy of the TNF-Kinoid in patients suffering from Crohn's Disease.

Consistent with the indications in the Company's announcement of 8th December 2010, at the end of December, Neovacs received consents from the regulatory authorities and ethics committees in both France and Belgium, allowing the start of patient recruitment for this study.

The double-blind, randomized, placebo-controlled TNF-K-005 study will recruit between 66 and 132 patients with moderate to severe Crohn's Disease (having a Crohn's Disease Activity Index, CDAI, of between 220 and 450) and who have failed treatment with a TNF inhibitor. The primary endpoint of the study is to measure the efficacy of the TNF-Kinoid in inducing clinical remission, defined as a CDAI of 150 or less. Other measures of clinical activity to be measured include clinical response, defined as a decline in CDAI of 100 points or more as compared to the value at study entry, mucosal healing measured by colonoscopy, and relevant biomarkers.

Final top-line results of the prior clinical study, TNF-K-001 were announced on 8th December. This study demonstrated a good safety profile for the TNF-Kinoid and that the 180mcg and 360mcg produced an antibody response to the TNF cytokine in patients. Further, a high rate of clinical response was observed, with nearly half the patients achieving clinical remission.

Details of these encouraging results will be the subject of an oral presentation at the ECCO (European Crohn's and Colitis Organization) Congress which takes place in Dublin from the 24th-26th February 2011. This annual event brings together the international thought leaders in gastroenterology.

"Starting the TNF-K-005 study is a major milestone for Neovacs, since it is the first placebo-controlled efficacy study of our TNF-Kinoid product candidate," commented Pierre Vandepapeliere, Neovacs' Chief Medical Officer. *"The study is designed to generate statistically significant clinical data to confirm the preliminary efficacy results seen in the prior study, TNF-K-001."*

"Crohn's Disease remains an area of serious unmet medical need, so research into new therapies is very important," stated Professor Paul Rutgeerts, head of the IBD research group at the Gasthuisberg University Hospital in Leuven, Belgium. *"Consequently, we are very happy to play a role in the clinical testing of the TNF-Kinoid developed by Neovacs."*

Starting 2011 after a very busy 2010, Neovacs now has four clinical trials in hand of its two most advanced product candidates:

- The Phase I/II TNF-K-001 study in Crohn's Disease, with topline results announced on the 8th of December, and detailed results to be presented at ECCO 2011 in February.

- The Phase IIa TNF-K-003 study in Rheumatoid Arthritis patients having failed a TNF inhibitor, initiated early in 2010.
- The Phase I/II IFN-K-001 Study, ongoing in lupus patients.
- The Phase IIa TNF-K-005 Study in Crohn's Disease patients having failed a TNF inhibitor, the start of which is announced today.

About Crohn's Disease

Crohn's is a chronic and progressive inflammatory disease of the gastro-intestinal tract associated with an autoimmune pathology. Crohn's manifests itself via a range of debilitating symptoms, including severe diarrhea, abdominal pain and cramping, intestinal strictures and fistulae and malnutrition. It is most frequently diagnosed in young adulthood. In the vast majority of cases, patients receive long-term treatment which focuses on suppression of the immune response, although surgery is also part of the therapeutic arsenal. The central role of TNF in the pathology of this disease has been confirmed by the clinical efficacy of monoclonal antibodies targeting TNF. Nonetheless, current medical options are limited, and in particular there is a need for drugs that can durably induce and maintain remission, a development eagerly awaited by both physicians and patients. According to Datamonitor, Crohn's Disease affects nearly 1 million people in the seven largest pharmaceutical markets.

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 α -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 has been completed and a Phase II trial in rheumatoid arthritis (RA) is 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 α -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 website at www.neovacs.com

Contacts

Press - Alize RP

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

Neovacs

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

Investors – Actifin

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