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Neovacs announces the completion of patient recruitment in its international Phase II clinical trial of TNF-Kinoid in Crohn's disease

Paris, December 15th 2011 - Neovacs (Alternext Paris: ALNEV), a biotech company focused on the development of active immunotherapies for the treatment of autoimmune and inflammatory diseases, today announced that it had completed patient recruitment in the first phase of its international TNF-K-005 Phase II clinical trial. The trial's results are expected in the second quarter 2012. The study's objective is to evaluate the therapeutic efficacy of TNF-Kinoid versus placebo in Crohn's disease patients having become resistant to anti-TNF drugs.

"TNF-Kinoid represents a novel potential treatment for patients suffering from Crohn's disease - a very debilitating, chronic condition that affects a total of around one million people in industrialized countries and for which there is not yet a lasting therapeutic solution", commented Professor Desreumaux, a practicing gastroenterologist at Lille Hospital and Director of the INSERM Department on Physiopathology for chronic inflammatory bowel diseases. Professor Matthieu Allez, a gastroenterologist at Paris' Saint-Louis Hospital added "*Current therapies have significant shortcomings and there is a major need for an innovative therapeutic approach."*

"The completion of patient recruitment in our Phase II trial of Crohn's disease is an important milestone for Neovacs: it testifies to the physicians' confidence in our approach and the technology's potential. We are looking forward to seeing the first study results (scheduled for the 2nd quarter 2012); the trial is designed to confirm the efficacy results observed in the prior TNF-K-001 study", commented Neovacs' CEO Guy-Charles Fanneau de la Horie.

Patients have been randomized in the trial in 7 European countries. The double-blind, placebo-controlled study includes over 60 patients suffering from moderate to severe Crohn's disease (defined as a Crohn's Disease Activity Index (CDAI)[1] of between 220 and 450) and who have lost response to at least one anti-TNF treatment. The trial's primary objective is to evaluate the TNF-Kinoid's ability to induce clinical remission (defined as a CDAI below 150). The final study results should be available in the 2nd quarter 2012. As a reminder, the TNF-K-005 trial might include two phases of 60 patients each, depending on the results obtained with the current first phase. If necessary to increase the statistical power, a second phase might be initiated at that point.

[1] The CDAI is a composite score for the quantitative rating of Crohn's disease symptoms

About Crohn's disease

Crohn's disease is a chronic, progressive, inflammatory condition of the gastro-intestinal tract that is autoimmune in origin. The pathology manifests itself via a range of debilitating symptoms, including severe diarrhea, abdominal pain/cramping, intestinal strictures and fistulae and malnutrition. It is most frequently diagnosed in young adults. In the vast majority of cases, patients receive long-term treatment that focuses on suppression of the immune response, although surgery is also part of the therapeutic arsenal. The central role of tumor necrosis factor (TNF) in this disease has been confirmed by the clinical efficacy of anti-TNF monoclonal antibodies. However, there are few treatment options at present; in many patients, disease activity is not adequately controlled are not sufficiently treated and thus the development of disease-modifying drugs for lasting remission is eagerly awaited by both physicians and patients. According to Datamonitor, Crohn's disease affects a total of around 1 million people in the industrialized world.

The Neovacs approach

Neovacs' innovative therapeutic approach (the Kinoid technology) stimulates the patient's immune system to produce antibodies and thus enables the patient to combat his/her disease.

Neovacs is developing two active immunotherapies based on Kinoid technology: TNF-Kinoid and IFNα-Kinoid.

TNF-Kinoid is being developed in 2 indications:

- ✓ In Phase II clinical trials in Crohn's disease, with results scheduled for April 2012. The Phase I/II results were highly promising, with prolonged remission in 50% of patients.
- ✓ In a Phase IIa clinical trial in rheumatoid arthritis. The results of this study will be announced in early January 2012.

About the TNF-Kinoid development program in Crohn's disease

The final results of the TNF-K-001 Phase I/II study (published on December 8, 2010) confirmed the TNF-Kinoid's good safety profile and its immunogenicity at doses of 180 and 360 mcg. It was particularly noteworthy that a high clinical response rate was observed, with a lasting clinical remission in half the patients at the two higher doses. These results were sufficiently encouraging to merit oral presentation at the major international Congress of the European Crohn's and Colitis Organisation in Dublin in February 2011 and during Digestive Disease Week in Chicago IL in May 2011.

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 IFNα-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.com

Contacts

Press – ALIZE RP
Caroline Carmagnol
+33 (0)1 42 68 86 43
caroline@alizerp.com.com

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

Investors – Newcap
Axelle Vuillermet
+ 33 (0) 1 44 71 94 93
avuillermet@newcap.fr