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INTERIM RESULTS FROM NEOVACS' PHASE II CLINICAL TRIAL IN CROHN'S DISEASE

Paris, 5th June 2012 – NEOVACS (Alternext Paris : ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases today announced the interim results of its Phase II clinical study TNF-K-005 in patients with Crohn's Disease who have failed therapy with at least one anti-TNF monoclonal antibody.

The interim analysis of the cohort of the first 60 patients did not show any statistically significant difference in terms of clinical remission between the Kinoid-treated group and the placebo group. The interim analysis did however demonstrate 3 important points that support further clinical development:

- **A statistically significant correlation between clinical remission and the level of antibodies induced by the Kinoid, which confirms the biological activity of the Kinoid. Specifically, in the Kinoid group, the patients achieving remission are those with the highest level of anti-TNF antibodies induced by the Kinoid.**

- **A major factor explaining non-response to the Kinoid is the ongoing presence of monoclonal antibodies at the time of entry into the study.**

- **The excellent safety profile of the TNF-Kinoid, consistent with the two previous studies.**

All these findings are subject to confirmation in the final phase of the study, results from which will be published in the fourth quarter of 2012.

Neovacs' TNF-K 005 Phase II clinical trial is a double-blind, placebo controlled study conducted in 60 patients with moderate to severe Crohn's Disease (a disease activity by CDAI [1] of between 220 and 450) active on entry and having failed at least one anti-TNF therapy. Patients were enrolled in 7 European countries.

[1] CDAI: Crohn's Disease Activity Index. A composite index quantifying Crohn's Disease activty

The presence of residual monoclonal antibody levels in a high proportion of patients was unexpected, given a "wash-out" period of several weeks. The residual antibody seems to have had a negative effect on the immune response and thus the clinical effect of the Kinoid, and so may have had a strong influence on the results of the trial. Neovacs has therefore decided:

1. Not to recruit the second cohort into the study, but rather to wait for the additional data that will be generated by the patients already enrolled : per the study protocol, patients who received three doses of the Kinoid have now received a fourth maintenance dose, while patients in the placebo arm have received three doses of the Kinoid The results of the second phase will be available in Q4 2012.
2. To design a new study which will exclude patients with residual anti-TNF monoclonal antibody levels.

"*The relationship between clinical remission and anti-TNF antibody titer induced by the Kinoid has been confirmed. The negative impact of residual anti-TNF antibodies on Kinoid immunization is an interesting scientific result, which will assist in the design of future studies. Moreover, taking into account the results seen in January in the study of the TNF-Kinoid in rheumatoid arthritis using the 360 mcg dose, we think we could improve both the response rate and the level of antibodies induced if we used this dose rather than the 180 mcg dose used in this study*." commented Guy Charles Fanneau de La Horie, Neovacs' CEO

"Today, thanks to the 3 studies that we have conducted with the TNF-Kinoid, we know that:

1. *The TNF-K is safe and well tolerated*
2. *The TNF-K is immunogenic and 360mcg is the more immunogenic dose*
3. *A clear relationship exists between TNF antibody titer and clinical remission*
4. There is a negative impact of *residual anti-TNF antibodies on Kinoid immunization, a factor that will be taken into account in the design of future studies.*

The data we expect by the end of the year will be very important to confirm these findings. "*We remain very confident in our Kinoid technology platform and the potential for active immunotherapy to become the next generation of treatments for chronic autoimmune diseases.*"

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.

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

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