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FINAL RESULTS OF THE PHASE II STUDY IN CROHN'S

Association between TNF-Kinoid induced antibodies and clinical remission in patients who have lost response to a monoclonal antibody TNF inhibitor

- The Kinoid has a very good safety and tolerability profile;
- The ability of the Kinoid to induce an immune response is confirmed.

Paris, November 20, 2012 – NEOVACS (Alternext Paris : ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases today announced the final results of the Phase II study of its TNF-Kinoid active immunotherapy in Crohn's Disease (TNF-K-005), in patients who had lost response to a monoclonal antibody TNF inhibitor. Final results show an association between antibodies titers induced by active immunization and clinical remission.

Guy-Charles Fanneau de la Horie, CEO of NEOVACS, commented: *"These results confirm a clear association between clinical remission and anti-TNF antibody induced by our TNF-Kinoid in patients who have lost response to a TNF inhibitor. Considering the complexity of the study population, and the fact that we used a dose that we now know to be suboptimal, we now have solid and very encouraging data in hand to support the next steps in the development of the TNF-Kinoid in Crohn's Disease and rheumatoid arthritis."*

TNF-K 005 Study Protocol

Neovacs' TNF-K 005 Phase II clinical trial is a double-blind, placebo controlled international study conducted in 60 patients with moderate to severe Crohn's Disease (a disease activity by CDAI [1] of between 220 and 450) having failed at least one anti-TNF therapy. Patients were enrolled in 7 European countries. The schedule of administration was 3 doses of 180 mcg of TNF-Kinoid on days 0, 7, 28 with a "cross-over" from day 84, with the placebo group from the first phase of the study receiving the Kinoid (3 injections) and the Kinoid group from the first phase getting a fourth dose of the Kinoid followed by placebo injections. The study blind was maintained during this second phase.

The interim results of the study reported in June 2012 revealed two important findings: 1) The presence of residual monoclonal antibody to TNF from a prior course of treatment interfered with the production of natural antibodies to TNF following Kinoid administration, and 2) the 180 mcg dose is too low to produce the best immune response.

The results presented today relate to the final phase of the study, after the "cross-over ".

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

Safety

The excellent tolerability and safety profile of the TNF- Kinoid is again confirmed. More than 100 patients have now been treated with a NEOVACS immunotherapy.

Immune response results: confirmation of TNF-Kinoid's immunogenicity

The final phase of the study demonstrated the good immunogenicity of the Kinoid. Over the study as a whole, an immune response was achieved in 65% of patients with active disease (CDAI >150) and no residual monoclonal antibody at the time of Kinoid administration. This finding is consistent with the data presented at the ACR meeting on 11 November in rheumatoid arthritis patients who have lost response to a biologic TNF inhibitor (Figure 1).

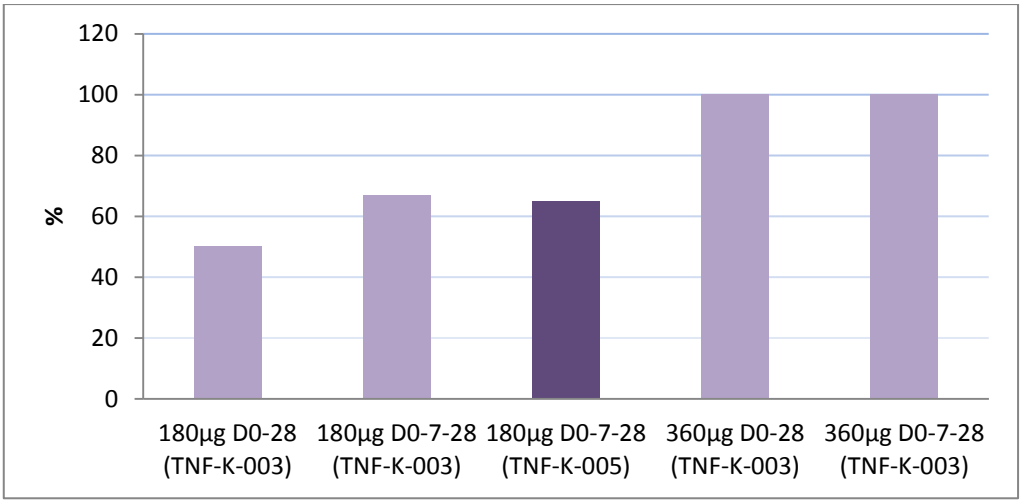

Figure 1 : Percent of TNF-resistant patients having an immune response to TNF-Kinoid

Further, the study presented at ACR clearly demonstrated that the 360 mcg dose produces both a higher rate of response to the Kinoid and higher levels of antibodies to TNF than the 180 mcg dose (Figure 2).

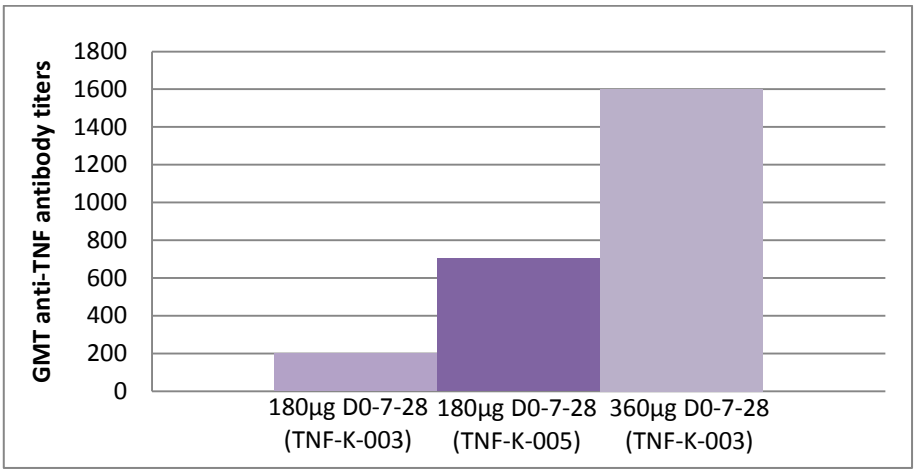

Figure 2 : Anti-TNF antibody geometric mean titers in TNF-resistant patients

The administration of the fourth dose at Day 84 caused a rebound in antibody titers with the peak higher than that seen after the three priming doses (Figure 3).

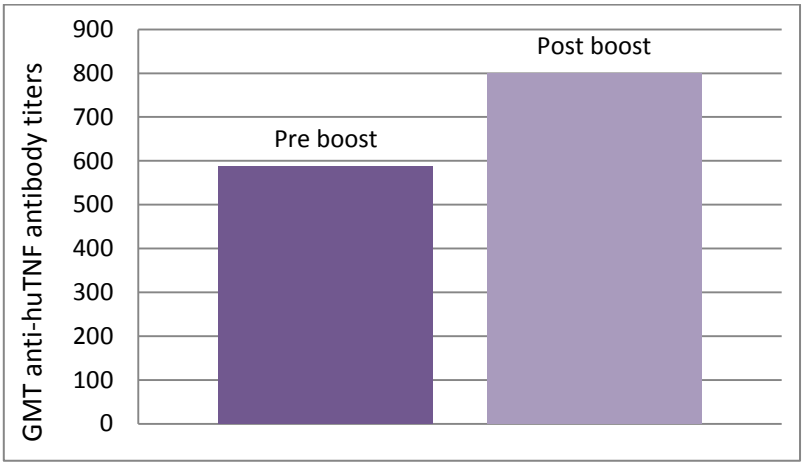

Figure 3 : Impact of boost on anti-TNF antibodies in patients with an immune response to the Kinoid, resistant to TNF treatment.

Clinical results: association between antibodies generated by active immunization and clinical remission

There is a clear association between antibodies induced by the TNF-Kinoid and clinical remission. In patients that received the placebo and with active disease (CDAI >150) at day 84, 33% of those having an immune response to the Kinoid and clear of residual monoclonal antibody were in clinical remission three months later, as opposed to none of the patients not having an immune response (Figure 4). Including the Kinoid patients who developed anti-TNF antibody and clear of residual monoclonal antibody, 27% of patients were in clinical remission versus 12.5% of the patients not having an immune response (Figure 5).

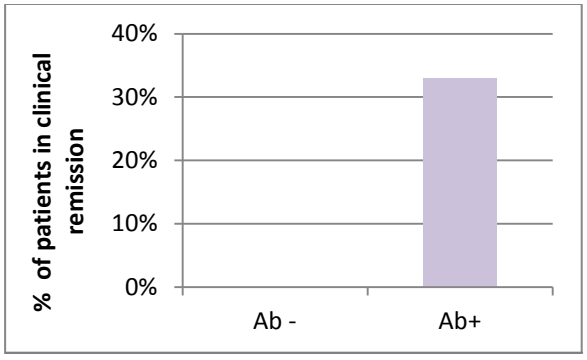

Figure 4: Clinical remission rate by antibody status, in patients with a CDAI>150 and no residual monoclonal antibodies, placebo to Kinoid group

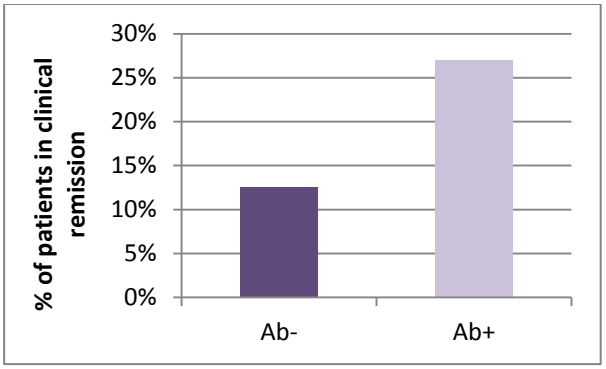

Figure 5: Remission rate by antibody status, in patients with a CDAI>150 and no residual monoclonal antibodies, both groups

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 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.fr

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