



## Encouraging results from the Phase I/II clinical trial of TNF-Kinoid in Crohn's Disease.

### Neovacs to present the key findings of the trial to an investor meeting.

Paris, December 8<sup>th</sup>, 2010 - Neovacs (Alternext Paris: ALNEV), a biotechnology company focused on active immunotherapy for autoimmune and inflammatory diseases and cancer, today announced the final results of its Phase I/II clinical trial of TNF-Kinoid which showed:

- the drug candidate's excellent safety profile in all subjects.
- an immune response to the drug as intended, and
- a high clinical response rate, with clinical remission (absence of symptoms) in almost half the patients.

The TNF-K-001 Phase I/IIa clinical trial was performed in 21 patients suffering from moderate to severe Crohn's disease (defined as a Crohn's Disease Activity Index (CDAI) of between 220<sup>(1)</sup> and 400). Each patient received three administrations of one of three dose levels of TNF-Kinoid (60 mcg, 180 mcg or 360 mcg) on days 0, 7 and 28, with four patients also receiving a maintenance dose at month 6. **The study's primary objective was to assess TNF-Kinoid's safety and its ability to induce an immune response to tumor necrosis factor (TNF).** The final results presented today confirm the drug candidate's excellent safety profile; no treatment-related serious adverse events, unusual infections or premature study withdrawals were recorded. Reactions to administration of the Kinoid (whether local or systemic) were mild, transient and limited to a few patients.

**In terms of immune response, in 17 of the 21 treated patients, TNF-Kinoid induced the production of anti-TNF antibodies.** Of the three patients receiving the lowest dose (60 mcg), only one mounted an immune response to TNF. In both the 180 and 360 mcg dose levels, 8 of the 9 patients in each group (89%) produced anti-TNF antibodies.

In terms of clinical response (at study week 12 and after 3 administrations of the drug), 76% of the patients showed a significant clinical improvement (defined as a 70-point drop in the CDAI) and 43% of these patients were in clinical remission (i.e. the absence of symptoms, as evidenced by a CDAI at or below 150).

*"These results are highly encouraging and promising. They constitute a key milestone for Neovacs and mark the start of our validation of this unique therapeutic approach based on active anti-cytokine immunization", commented Neovacs CEO Guy-Charles Fanneau de La Horie. "The study enabled us to gather extensive data on TNF-Kinoid's safety and immunogenicity. Our ongoing clinical development program is designed to confirm these results in the months ahead, as announced at the time of our IPO:*

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<sup>(1)</sup>The Crohn's Disease Activity Index is a quantitative, composite index of disease severity.

*we are in the process of initiating a double-blind, placebo-controlled Phase II study in Crohn's disease",* he added.

*"Despite progress in treating Crohn's Disease, both patients and doctors want to see new treatments,"* noted Professor Antoine Cortot, Head of the Gastroenterology Department at Lille Hospital- France. *"These first results with the TNF-Kinoid in 21 Crohn's patients are promising; they now need to be confirmed in a larger number of patients"*

### **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 $\alpha$ -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 and a Phase II trial in rheumatoid arthritis (RA) are 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 $\alpha$  -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](http://www.neovacs.com)**

#### **Disclaimer**

This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in Neovacs ("the Company") in any country. This press release contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. Unfavorable developments in connection with these and other risks and uncertainties described, in particular, in the Company's prospectus prepared in connection with its IPO and on which the French *Autorite des marches financiers* ("AMF") granted its visa no. 10-085 on April 8, 2010, could cause the Company to fail to achieve the objectives expressed by the forward-looking statements above.

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