Neovacs achieves significant milestones in two clinical trials

- Successful completion of patient recruitment in the company's Phase I/II trial of TNFα-Kinoid™ in Crohn's disease
- Recruitment of the first patient into the Phase I/II trial of IFNα-Kinoid™ in lupus

The 3 clinical trials are hitting their milestones according to the planned schedule

Paris, May 17, 2010 – 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 that it has recruited the last two patients into its Phase I/II clinical trial of anti-TNFα Kinoid™ (TNF-K) in Crohn's disease and has administered interferon-alpha Kinoid™ (IFN-K) to the first patient in its Phase I/II trial in lupus.

"These two milestones are consistent with our expectations at the time of our IPO in April; our clinical development programs are hitting their milestones on schedule. The final results of the Phase I/II trial of TNF-K in Crohn's disease should be available by the end of this year. We now have three clinical studies underway, with TNF-K in Crohn's disease (Phase I/II), TNF-K in rheumatoid arthritis (Phase II) and IFN-K in lupus (Phase I/II)", commented Neovacs CEO Guy-Charles Fanneau de La Horie.

About the Phase I/II trial of TNF-K in Crohn's disease

The trial is an open-label, non-controlled, dose-escalation Phase I/II study with 3 dose levels of TNF-K (60, 180 and 360 mcg) administered at 0, 7 and 28 days or 0, 7, 28 and 168 days in patients with moderate-to-severe Crohn's disease. Two patients have received three 60 mcg doses, one has received four 60 mcg doses, seven have received three 180 mcg doses, two have received four 180 mcg doses, two have received four 360 mcg doses and seven have received three 360 mcg doses. The last 2 patients recruited will both receive three 360 mcg doses. No product-related serious adverse events have been reported and none of the patients has withdrawn from the study for tolerability or safety reasons. The study's primary objective is to assess the Kinoid™'s safety and its ability to induce an immune response to tumor necrosis factor alpha (TNFα). A secondary objective is to look at the therapeutic effect, as measured by the clinical disease score and markers of disease activity.

"This study is the first to have produced positive immunologic and clinical results with an active, anti-cytokine immunotherapy in the treatment of a chronic inflammatory disease. The preliminary results are very encouraging and additional studies are now underway or being planned, in order to confirm and complete these observations", added Pierre Vandepapelière, Chief Medical Officer at Neovacs.

Neovacs has just published a poster on the latest clinical results for TNF-K in Crohn's disease at the Digestive Disease Week 2010 convention (DDW 2010) in New Orleans, LA, USA. The work was selected as a "Poster of Distinction".

About the Phase I/II trial of INF-K in lupus

This double-blind, dose-escalation Phase I/II study will recruit up to 28 patients, with randomization by dose level. Study subjects must present moderate disease symptoms. The study's primary objective is to gather information on the treatment's safety and tolerability. Secondary objectives include measurement of the immune response to the Kinoid™, the disease activity index and disease markers related to interferon-alpha (IFNα). Depending on patient recruitment, the study's preliminary results (after the blinding codes have been broken) may be available in early 2011. Neovacs has already obtained approval for the trial from the regulatory authorities in France, Belgium and Bulgaria and clinical trial applications have been filed in other European countries.

"Lupus patients are still facing significant unmet medical needs because there haven't been any new drugs launched in this indication for several decades now. Our approach could provide major benefits in terms of efficacy, safety and ease of treatment. This study highlights our commitment to improving the standard of care for these patients", stated Neovacs CEO Guy-Charles Fanneau de La Horie.

"This first-in-man administration constitutes a key milestone in the clinical development of IFN-K and provides a further illustration of the medical community's interest in the Kinoid™ approach", added Pierre Vandepapelière, Chief Medical Officer at Neovacs.

About Neovacs

Neovacs is a biotechnology company focused on an active immunotherapy technology platform (Kinoids™) with applications in autoimmune diseases and other chronic conditions. It was founded as a spin-off from Pierre & Marie Curie University in Paris by Professor Daniel Zagury, MD, one of the world's leading immunologists. Neovacs' current portfolio consists of 3 drug candidates: TNFα-Kinoid™, IFNα-Kinoid™ and VEGF-Kinoid™. The company's lead immunotherapy program (TNFα-Kinoid™) is targeting TNFα-mediated chronic inflammatory diseases. For TNFα-Kinoid™, the last two patients have just been recruited into a Phase I/II clinical trial in Crohn's disease and a Phase II trial in rheumatoid arthritis (RA) is also underway. The latter clinical study is also the focus of a collaboration with the diagnostics company BMD, with the goal of developing theranostic tools for personalized care in RA. At the end of 2008, TNFα-Kinoid™ was selected by Thomson Reuters as the most promising drug in Phase II clinical trials. Patient recruitment has started in a Phase I/II trial of Neovacs' second product candidate (IFNα 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 web site at www.neovacs.com.

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