



### **Neovacs achieves key clinical milestones**

- IFN $\alpha$  Kinoid for lupus: Recruitment and dosing of first dose cohort in Phase I/II trial complete; DSMB authorizes initiation of dosing in second dose cohort.
- TNF $\alpha$  Kinoid for rheumatoid arthritis: Recruitment and dosing of first dose cohort in Phase IIa trial complete; recruitment of second cohort at higher dose level initiated.

**Paris, July 21, 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 the achievement of important milestones in its clinical development programs.

#### **Consent to proceed to higher dose in the Phase I/II study of IFN $\alpha$ Kinoid in lupus patients**

Recruitment and dosing of the first dose cohort in the Phase 1/2 study of IFN $\alpha$  Kinoid in lupus patients are complete, and the data related to these patients has been reviewed by the Data and Safety Monitoring Board (DSMB), an independent committee which is responsible for overseeing the conduct of the study and in particular for patient safety. As a first in man study of a novel immunotherapy, the trial design calls for DSMB review and consent prior to the initiation of each escalating dose group. As a result of the DSMB's review, this consent has now been received and screening of patients for the second cohort is underway. Preliminary results from this study are expected in Q1 2011.

*"We are very pleased with the progress of this trial to date,"* commented Pierre Vandepapeliere, Neovacs' Chief Medical Officer *"In particular, the DSMB's consent to recruit patients into a higher dose group is indicative of the absence of any serious safety concerns so far."*

#### **The Phase IIa study of TNF $\alpha$ Kinoid in rheumatoid arthritis patients also advances to higher dose group**

Concerning the ongoing Phase 2 study of TNF $\alpha$  Kinoid in patients with rheumatoid arthritis who have failed a TNF $\alpha$  inhibitor and have antibody to the drug they failed, recruitment and dosing of the first dose cohort have been completed. Following a review of the safety data that raised no concerns, recruitment at the second dose level is being initiated. Preliminary data from this study is expected to be available in Q2 2011. This study is part of a collaborative program with bmd, a French diagnostics company, and is financed in part by Oséo/ISI, the French state innovation agency.

Regarding the ongoing Phase 1/2 study of TNF $\alpha$  Kinoid in Crohn's disease, this trial is fully enrolled as previously announced and patient follow-up continues, with final data expected to be available by the end of 2010 as planned.

*"We continue to make good progress in our clinical programs"* noted Guy-Charles Fanneau de La Horie, CEO of Neovacs *"Importantly, we are on track to deliver the multiple clinical trial datasets in H1 of 2011, as promised during our IPO process earlier this year."*

#### **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 nine have received 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.

#### **About TNFα-dependent autoimmune diseases**

These diseases affect the bones and joints (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, etc.), the digestive tract (Crohn's disease and hemorrhagic rectocolitis) and the skin (psoriasis). In seven major developed countries alone (USA, Japan, the UK, Germany, France, Italy and Spain), there are 9.3 million people with bone and joint diseases, 2.1 million with digestive diseases and 16.5 million with psoriasis (Datamonitor, 2007).

#### **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.

#### **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™, a Phase I/II clinical trial in Crohn's disease and a Phase II trial in rheumatoid arthritis (RA) are 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. Patient recruitment is ongoing 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](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 *Autorité des marchés 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.

#### **Investor Relations**

##### **Neovacs**

Guy-Charles de La Horie

+33 (0) 1 53 10 93 00

[gcdelahorie@neovacs.com](mailto:gcdelahorie@neovacs.com)

##### **Actifin**

Nicolas Meunier

+ 33 (0) 1 56 88 11 11

[nmeunier@actifin.fr](mailto:nmeunier@actifin.fr)

#### **Press Relations**

##### **Neovacs**

Piers Whitehead

+33 (0) 1 53 10 93 08

[pwhitehead@neovacs.com](mailto:pwhitehead@neovacs.com)

##### **Alize RP**

Caroline Carmagnol

+33 (0) 6 64 18 99 59

[caroline@alizerp.com](mailto:caroline@alizerp.com)