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New promising data in the phase I/II clinical trial in Lupus patients: Data from the last cohort of patients (240 mcg) confirm the safety, immunogenicity and pharmacodynamic of IFN-K

Paris, 26th July 2011 - 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 published the data of the last cohort of patients in a phase I/II study with IFNα-Kinoid in Lupus patients. These patients had received 240 mcg of IFN-K, the highest dose of IFN-K tested. These preliminary confirm those which had been presented at the 8th European Lupus Meeting in Porto on April, the 8th 2011.

These new results confirm the previous set of data generated at lower doses of IFN-K:

- **IFN-K is well tolerated**
- **IFN-K, at the dose of 240 mcg, induced the production of antibodies to interferon α in all patients. In some patients, these antibodies could be measured as soon as on day 28, i.e. after the first 2 injections.**
- **IFN-K generated a significant downregulation of some overexpressed genes associated with interferon α and lupus.**

Another very promising piece of news is that with a longer follow-up it was found out that IFN-K at all doses induced the production of anti-interferon α antibodies in all patients, instead of 80% of patients as previously observed.

This set of data highlights further the potential of Neovacs' second drug-candidate, IFN-K in the treatment of lupus.

By way of reminder, the IFN-K-001 Phase I/II study is a double-blind, placebo-controlled, dose-escalation design testing four different IFNα-Kinoid dose levels. All patients recruited have mild to moderate lupus, defined as a SLEDAI[1] score of between 4 and 10. The main endpoints of the trial are the safety and tolerance of the IFNα-Kinoid, its capacity to induce an antibody response to IFNα, the evolution of clinical disease scores (such as SLEDAI) and biomarkers for disease activity, including the interferon signature which measures changes in the activity of genes that are overexpressed in Lupus. Results for the highest dose group of 8 patients at 240 mcg (including 2 placebo patients) are presented today and confirm data previously presented with the first three dose groups (30, 60 or 120 mcg of the Kinoid), comprising 20 patients.

Highlights of the results in the fourth cohort

The IFNα-Kinoid is highly immunogenic:
Antibodies to IFNα have been induced in 100% (6) patients treated with the Kinoid. Production of anti-interferon α was quick and titers were high. This very good score highlights the clear induction of an immune response with the IFNα-Kinoid.

[1] Systemic Lupus Erythematosus Disease Activity Index

The IFNα-Kinoid is well tolerated

The dose of 240 mcg of IFN-K was well tolerated. Two serious adverse events (lupus flares) were recorded and their causes were quickly identified: One of them occurred in the placebo group and the other one in a patient who had spontaneously interrupted her steroid treatment after the first injection of kinoid.

Significant reduction in interferon signature in patients treated with the IFNα-Kinoid:

The IFN-K generated a significant downregulation of overexpressed genes associated to interferon α and lupus.

Final results of the Phase I/II with IFN-K in lupus will be published by the end of Q3 2011

The thorough analysis of the data in all 28 patients is on-going. It will be presented by Neovacs in scientific meetings.

About lupus

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body leading to widespread inflammation and tissue damage. Prevalence estimates vary widely, and range as high as 1.5 million in North America (the Lupus Foundation of America) and 5 million worldwide. The Center for Disease Control estimates a prevalence between 322,000 and one million with definite or probable SLE in the US. Lupus disease may first occur at any age, though peak diagnosis is between the ages of 15 and 40. It is far more common in women than men. People with SLE may experience fatigue, pain or swelling in joints, skin rashes, and fevers. It can also affect the lungs, kidneys, and blood vessels. It remains an area of significant unmet medical need. Scientists have highlighted the overproduction of the interferon alpha cytokine as a key factor in the causation and development of the disease.

The market of lupus treatments is estimated by analysts to be several billion US$ worth.

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® proprietary technology, protected by five patent families, aims to induce a polyclonal immune response from the patient's own immune system targeting an over-expressed cytokine. Neovacs®' current portfolio consists of 2 drug candidates which are tested in clinical studies: TNF-Kinoid and IFNα-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 has been completed and Phase II trials in rheumatoid arthritis (RA) and Crohn's Disease are ongoing. The RA 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. IFN-K is developed in the treatment of lupus.

For more information, visit the Neovacs® website at www.neovacs.com

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