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IFN-K-001 Phase I/II study in lupus: final results presented today at the American College of Rheumatology (ACR) Annual Scientific Meeting in Chicago in both an ACR press conference and oral session

- Excellent tolerability
- Strong immunogenicity
- Significant activity on lupus biomarkers

Paris, 8th November 2011: Neovacs® (Alternext Paris : ALNEV), a biotech company focused on an active immunotherapy technology platform (Kinoids®) with applications in the treatment of autoimmune and inflammatory diseases and cancer, is pleased to announce the results of its IFN-K-001 clinical study in lupus, presented today at the prestigious ACR Annual Scientific Meeting.

Professeur Frederic Houssiau, Head of the Rheumatology Department at the Catholic University of Leuven in Brussels, Belgium, and the Principal Investigator of the study, commented: *“Lupus is a serious and complex disease that remains a major challenge for physicians. Interferon alpha plays a key role in the disease and so treatments that neutralize it have a therapeutic logic. We have shown that Kinoid® treatment reduces the gene dysregulation associated with the overexpression of IFN α , and that this is reflected in certain disease markers. These results are very encouraging in the context of this novel therapy”.*

On the subject of the disease marker results in particular, Dr. Pierre Vandepapelière, Neovacs® Vice-President of Clinical Development, added: *“The clear correlation between antibody levels induced by the Kinoid® and the improvements in gene dysregulation, taken with the further association with changes in anti-dsDNA antibody and Complement C3 levels are critical indicators of promising therapeutic activity”.*

The detailed analysis of the study shows that **100%** of patients who received the IFN α -Kinoid® produced antibodies to IFN α . It also shows that administration of the IFN α -Kinoid®, especially at the higher doses, 120 mcg and 240 mcg, has a statistically significant ($p=0.0001$) impact on the dysregulation of genes related to interferon α (the interferon signature) as well as those associated with lupus disease (the lupus signature). A further new and important finding speaks to the first indication that the Kinoid® treatment has a favorable impact on the underlying markers for disease activity: specifically, there is a statistically significant ($p=0.04$) relationship between the level of anti-IFN α antibody and the increase in complement C3, an established biomarker in lupus. Similarly, a very interesting association has been observed between the reduction of the

IFN α gene signature and a fall in the levels of antibodies to dsDNA, another key marker for lupus disease activity.

The selection of Neovacs®' results for oral presentation to the medical and scientific attendees at the ACR meeting, as well as their inclusion in the ACR's morning press conference, speaks to the level of scientific interest in the IFN α -Kinoid® approach to treating lupus.

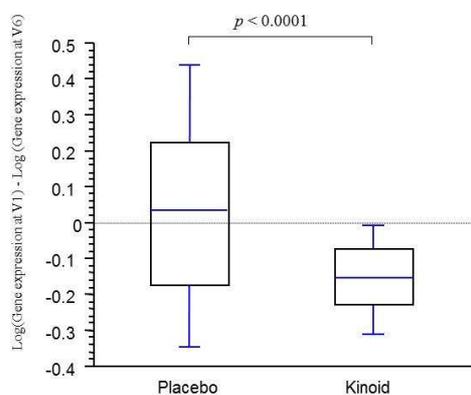
As a reminder, the IFN-K-001 study of IFN α -Kinoid® was conducted in 28 patients. The study was double-blind, randomized and placebo-controlled, and tested four dose levels. Product was administered at days 0, 7, and 28, with a fourth injection being given to half the patients at Day 84. All the patients enrolled had mild to moderate disease activity, defined as a SLEDAI¹ score of between 4 and 10. 7 of the 28 patients received the placebo.

Good product tolerance confirmed

The data now available, for all patients for at least three months and for some patients for 15 months of follow-up, confirms the very good safety profile of the IFN α -Kinoid®. The only serious adverse event considered as associated with the product was a lupus flare: the patient in question stopped taking her corticosteroid medication two days after receiving her first Kinoid dose and without reference to her treating physician. The patient was withdrawn from the study.

Antibodies to IFN α raised by the IFN α -Kinoid® have a significant impact on multiple disease markers

The activity of the antibodies to IFN α induced by Kinoid® administration is confirmed by the fact that a reduction in the dysregulation of lupus-associated genes is clearly observable. Similarly, a dose effect is also observable, since there is a correlation between the dose of IFN α -Kinoid® administered, the level of antibodies induced as a consequence and the reduction in dysregulation seen in the relevant genes.



Change in dysregulation of 250 lupus-associated genes

A further analysis has been conducted of a marker recognized as being a good indicator of the severity of disease activity, complement C3, where lower levels are associated with greater disease severity. The analysis demonstrated a statistically significant relationship between antibodies to IFN α and increases in C3 levels.

¹ Systemic Lupus Erythematosus Disease Activity Index

Another marker associated with disease severity in lupus is levels of antibodies to dsDNA. In patients that developed antibody to IFN α , there was an association between the reduction in lupus-associated gene dysregulation and a reduction in levels of antibody to dsDNA.

Commenting on the final results of the IFN α -Kinoid[®] Phase I/II study, Guy-Charles Fanneau de La Horie, Neovacs[®] CEO, said: *“We are very honored to have our work in lupus selected for presentation at ACR and included in this morning’s press conference: it is a welcome recognition by the experts of the American College of Rheumatology for our work against this disease and for our novel active immunotherapy approach to it”.*

Based on these excellent results, Neovacs[®] is working with leading experts in lupus to design the next step in the IFN α -Kinoid[®]’s clinical development plan.

The press release issued today by the American College of Rheumatology is available on Neovacs[®]’ website.

About lupus

Systemic Lupus Erythematosus (SLE) is a chronic, life-threatening 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 for lupus treatments is estimated by analysts to be potentially worth several billion US\$.

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 being tested in clinical studies: TNF-Kinoid[®] and IFN α -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 α -Kinoid[®] is being developed for the treatment of lupus.

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

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