



## NEOVACS ANNOUNCES THE PUBLICATION OF A PNAS ARTICLE ON ANTI-IFN $\alpha$ KINOID ACTIVE IMMUNIZATION IN LUPUS

These experiments suggest that IFN $\alpha$ -kinoid-based active immunization may represent a safe and effective strategy for treating Systemic Lupus Erythematosus

**Paris, March 16<sup>th</sup> 2009** -- Neovacs, a biotech company pioneering the development of anti-cytokine and anti-viral regulation protein therapeutic vaccines, today announced the publication of an article on anti-IFN $\alpha$  kinoid active immunization in the March 11 edition of the prestigious journal PNAS (the Proceedings of the National Academy of Sciences of the USA). In an article entitled "IFN $\alpha$  kinoid vaccine-induced neutralizing antibodies prevent clinical manifestations in a lupus flare murine model", Prof. Daniel Zagury MD and colleagues demonstrate the efficacy of an anti-IFN $\alpha$  kinoid active immunization approach in a mouse model of systemic lupus erythematosus (SLE, also referred to simply as "lupus").

Lupus is a frequent, life-threatening, chronic auto-immune disease which strikes up to 3 million people in the seven major developed countries (source: Datamonitor, 2007). It can affect any part of the body but mostly damages the heart, joints, skin, lungs, blood vessels, liver, kidneys and nervous system. The course of the disease is unpredictable, with periods of illness (called "flares") alternating with remissions. There is currently no cure and all available treatments are symptomatic, i.e. they treat the symptoms but not the underlying disease. Lupus can be fatal. The cause is not known but type I IFNs (IFN $\alpha$  and  $\beta$ ) have recently been described as key agents in the etiopathogenic process.

In the PNAS article, Zagury *et al.* report that an IFN $\alpha$ -derived immunogen called IFN $\alpha$  kinoid (a heterocomplex of IFN $\alpha$  and keyhole limpet hemocyanin) delayed and/or prevented the manifestations of lupus (including proteinuria, histological lesions and death triggered by IFN $\alpha$  Adv challenge) in NZB/W mice. The IFN $\alpha$  kinoid acted by triggering a strong IgG antibody immune response targeted specifically against IFN $\alpha$ . Importantly, no cellular immune response against IFN $\alpha$  was observed, as demonstrated by the lack of T cell proliferation after stimulation of splenocytes from immunized mice by the cytokine.

Interestingly, the mice fell in two groups, according to their immune response to the IFN $\alpha$  kinoid: good responders (IC<sub>50</sub>  $\geq$ 800) and low responders (IC<sub>50</sub> <800). All but one of the good responders survived, whereas all non-responders died of kidney failure. More importantly, no clinical or histopathological lesions could be detected in half the surviving animals. By extrapolating, it can therefore be supposed that IFN $\alpha$  protective effect of against proteinuria and death is associated with neutralizing antibody levels above a certain threshold.

*"These experiments are very encouraging. They show that IFN $\alpha$ -kinoid-based immunization may represent an innovative strategy for treating lupus. Indeed, other experimental data due to be soon published suggest that excessive IFN  $\alpha$ , overproduced during human lupus, can be neutralized by the antibodies generated after immunization with an IFN $\alpha$ -kinoid. We hope that clinical trials in man will be initiated rapidly"* commented Professor Zahir Amoura at France's National Reference Centre for Lupus and Antiphospholipid Syndrome at Pitié-Salpêtrière Hospital in Paris.

## **About Neovacs**

Neovacs is a spin-off from the Pierre & Marie Curie University in Paris and was founded on 1993 by Professor Daniel Zagury, one of France's most eminent immunologists and AIDS experts. Neovacs holds a broad patent portfolio and is developing several therapeutic vaccines for the treatment of AIDS, cancer and auto-immune & allergic diseases. Neovacs is acknowledged as a pioneer in the development of novel therapeutic vaccines against human cytokines (kinoids) and immunosuppressive viral proteins (toxoids). At present, monoclonal antibodies are widely used to neutralize cytokines and treat patients suffering from cytokine-related diseases. In contrast to exogenous therapies with monoclonal antibodies, Neovacs' therapeutic vaccines induce a powerful, natural polyclonal antibody response in the patient.

Neovacs' key investors are Truffle Capital, Novartis Venture Fund and OTC Asset Management.

Neovacs' most advanced program (the TNF $\alpha$  kinoid) is currently being tested in a Phase I/II clinical study in patients suffering from Crohn's Disease. As part of a collaboration with the company bmd, Neovacs recently received significant public financial support from Oséo (the French state innovation agency) for a Phase II study with TNF $\alpha$  kinoid in patients suffering from rheumatoid arthritis and who have developed an immune response against the monoclonal antibodies used to treat the condition. The IFN $\alpha$  kinoid program is part-funded by the French National Research Agency (ANR).

For further information on Neovacs, visit the website: [www.neovacs.com](http://www.neovacs.com)

*Disclaimer: the development of new drug technologies is difficult, erratic and unpredictable. Neovacs' forecasts and future economic performance depend on research that has yet to be performed and on a number of other factors. The company's future economic performance may differ significantly from that currently forecast.*

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