



## **Néovacs, a biotechnology company, begins a phase I/II clinical trial with the candidate TNF $\alpha$ -kinoid for the treatment of Crohn's disease**

This phase I/II study is the first administration in humans of a kinoid

**Paris, October 23, 2008** – Néovacs, ([www.neovacs.com](http://www.neovacs.com)), a leading biotechnology company in the development of anti-cytokine and anti-protein viral regulation therapeutic vaccines to treat certain cancers and inflammatory diseases, announced that it had begun a phase I/II clinical study at three study centres in South Africa with the candidate TNF $\alpha$ -kinoid, a therapeutic vaccine for the treatment of TNF $\alpha$  dependent auto-immune diseases such as rheumatoid arthritis, Crohn's disease and psoriasis. This study, to be conducted on patients suffering from Crohn's disease, will relate to the identification of the optimal immunogenic dosage for neutralizing TNF $\alpha$ .

*"We are delighted to have accrued the first patient in this phase I/II study, which marks a key step in the development of the TNF $\alpha$ -Kinoid", emphasises Guy-Charles Fanneau de La Horie, CEO of Néovacs. "Active immunisation is one of the most promising ways forward in the treatment of auto-immune diseases and TNF $\alpha$ -kinoid has the potential to become a very interesting therapeutic option for patients suffering from TNF $\alpha$  dependent auto-immune diseases. A limited number of administrations (3 to 4 per year) should suffice to control the disease, a huge advantage compared to existing treatments, which are a burden on our health system and heavy for patients – especially since many patients eventually cease to respond to these treatments", adds Doctor Pierre Vandepapeliere, Chief Medical Officer of Neovacs.*

*"The therapeutic options for patients suffering from TNF $\alpha$  dependent auto-immune diseases are unfortunately very limited and the active immunisation with TNF $\alpha$ -kinoid approach represents a notable and unique innovation among the products under development", Professor C-M. Boissier, Head of the Department of Rhumatology at Hopital Avicenne in Bobigny, stresses.*

This study will include between 12 and 18 patients with an active form of Crohn's disease. The study will follow a methodology of increasing doses and the immunogenicity being evaluated during the following months. These first results are expected in 2009. The aim of this study is to demonstrate the innocuousness of the therapeutic vaccine and to identify the optimal immunogenic dose which causes the appearance of anti TNF $\alpha$  neutralising antibodies. This phase I/II study is the first administration in humans of a kinoid, a heterocomplex compound formed from an inactivated targeted cytokine (TNF $\alpha$  in this specific case) and a carrier protein, KLH (Keyhole Lymphet Hemocyanin).

### **About TNF $\alpha$ dependent auto-immune diseases**

These diseases are mainly articular (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis); digestive (Crohn's disease and haemorrhagic rectocolitis); and cutaneous (psoriasis). In the 7 main developed countries alone (USA, Japan, GB, Germany, France, Italy and Spain), there are 9.3 million people suffering from articular diseases, 2.1 million from digestive diseases and 16.5 million from psoriasis (Datamonitor, 2007).

## **Existing treatments**

These treatments include: AINS (acetylsalicylate, etc.), corticosteroids, methotrexate type immunosuppressants and, more recently, anti-TNF $\alpha$  biological agents such as monoclonal antibodies (infliximab, adalimumab) and fusion proteins (etanercept).

Anti-TNF $\alpha$  biological agents, which appeared in the 2000s, have revolutionised the treatment of TNF $\alpha$  dependent auto-immune diseases. These products, of which there are currently three on the market, generated a turnover of almost US\$10 billion in 2007, with a quasi-equivalent distribution of market shares. A recent study (Pharmacor, Emerging Immunomodulators, 2008) is forecasting sales of close to US\$17 billion in 2017, for all immunomodulators, of which US\$6 billion for new products.

Néovacs is currently the leader in anti-cytokine therapeutic vaccination with three products under development: an anti-TNF $\alpha$  vaccine, an anti-VEGF vaccine developed for cancer and DMLA and an anti-IFN $\alpha$  vaccine developed for Lupus. Néovacs holds 16 patents which protect the anti-cytokine immunisation approach and the different vaccines.

In 2007 Néovacs carried out a major capital increase of more than 14 million euros, in which Novartis Venture Fund played the leading part. Truffle Capital, an investor and majority shareholder since 2003, reinvested in Néovacs to the tune of over 4 million euros. OTC Asset Management also participated in this operation.

## **About Neovacs:**

Neovacs, a spin-off from the Pierre & Marie Curie University in Paris, 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. For further information on Neovacs, visit our web site: [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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