



Press release

Swissmedic grants approval for a clinical study of Neovacs' TNF α - kinoid candidate for the treatment of Crohn's disease.

Paris, June 2, 2009 -- Neovacs, a biotechnology company developing proprietary immunotherapeutics for autoimmune and chronic diseases, today announced that Swissmedic (the Swiss regulatory authority for medicinal products) has granted clearance for the clinical study of its TNF α -kinoid candidate in patients with moderate-to-severe Crohn's disease. The TNF α -kinoid is currently being evaluated in a Phase I/II clinical study in South Africa. Following the receipt of Swissmedic's consent, Neovacs now plans to add two Swiss sites to the ongoing trial during the month of June.

Néovacs CEO Guy-Charles Fanneau de La Horie commented: *"Swissmedic's clearance is the first of several important clinical and regulatory milestones that we expect to achieve this year. Based on the encouraging progress to date, we plan to expand clinical testing of the TNF α - kinoid to additional indications in rheumatoid arthritis and psoriasis. We also expect to file an IND for our second product candidate (IFN α kinoid, for lupus) later this year"*.

The ongoing Phase I/II dose-escalation trial in South Africa is recruiting between 12 and 18 patients with active Crohn's disease and is designed to evaluate the kinoid's safety and immunogenicity. Preliminary results are expected in the second half of June.

About TNF α -dependent autoimmune diseases

These diseases variously affect the bones & joints (rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis), the digestive tract (Crohn's disease and hemorrhagic colitis) and the skin (psoriasis). In the 7 main developed countries alone (USA, Japan, the UK, Germany, France, Italy and Spain), there are 9.3 million people with bone & joint diseases, 2.1 million with digestive diseases and 16.5 million with psoriasis (Datamonitor, 2007).

About Neovacs

The biotechnology company Néovacs is focused on an active immunotherapy technology platform with applications in autoimmune disease 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.

The company's lead program (an immunotherapy targeting certain inflammatory diseases) is currently in a Phase I/II study in subjects with Crohn's disease. This product candidate is also the subject of a collaboration with the diagnostics company BMD, with the objective of developing theranostic tools for personalized care.

Néovacs' near-term milestones include clinical proof of concept for its lead product (mid-2009), the expansion of the lead clinical program into new indications (H2 2009) and the initiation of clinical trials of a second product - an immunotherapy targeting Lupus disease (H2 2009). The company's R&D has also generated a broad patent estate.

Disclaimer: drug development is an inherently uncertain and unpredictable process. Neovacs' forward-looking statements depend on research that has yet to be performed and on a number of other factors. As a consequence, the company's future performance and financial results may differ significantly from that currently forecast.

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