Neovacs obtains FDA "Fast Track" designation for IFNα Kinoid in Lupus (SLE)

Paris and Boston, December 7, 2016 – Neovacs (Alternext Paris: ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted "Fast Track" status to IFNα Kinoid in Lupus, the most advanced therapeutic vaccine issued from Neovacs R&D.

The FDA's "fast track" designation is granted to therapies in development that target severe diseases or those that are life threatening and which have shown their ability to address an unmet medical need, based on clinical data. This status facilitates exchanges with the FDA, accelerates the further product development and allows for a priority review of the product registration file. As a result of this designation, Neovacs has the best conditions to allow faster access to the IFNα Kinoid for American patients.

Neovacs is currently enrolling patients in an international Phase IIb trial (IFN-K 002) in Lupus (SLE), an autoimmune disease that is chronic and very invalidating and for which current treatments do not offer a satisfying therapy. The objective of this trial is to measure biological and clinical efficacy in moderate to severe SLE patients. This study, which has already recruited more than half of its targeted 178 patients, is underway in 21 countries in Europe, Asia, Latin America and the United States.

Miguel Sieler, CEO of Neovacs, commented: *"This announcement follows the IND obtained in April this year. It is the second favourable notification by the FDA to Neovacs in the course of 2016. We are proud to receive once again from the FDA the confirmation of the innovative character of our therapeutic approach."*

Dr. Therese Croughs, CMO of Neovacs, added: "*This "Fast Track" designation reinforces our confidence in the therapeutic potential of IFN Kinoid as a treatment for Lupus. Today, the available treatments only aim to reduce the inflammation, to alleviate the symptoms and are associated with significant side effects."*

About Neovacs Technology

Neovacs targets pathologies associated with an overproduction of endogenous cytokines. This technology is based on active immunotherapy to generate an immune response through the administration of an immunogenic complex involving the target cytokine (for example **IFNα**, **manufactured by 3P Biotechnology**) to

a carrier protein (for example **KLH**, **produced by our Partner Stellar Biotechnology**). The intramuscular injection of this Kinoid induces an immune response and stimulates the production of polyclonal antibodies against the target cytokines. It is thus possible to block cytokine overproduction and its biological effects. Several autoimmune and inflammatory diseases (systemic lupus erythematosus, psoriasis, Type 1 diabetes etc.) are characterized by a disorder of cytokines that are found produced in excess (ex: IFNa). This overproduction will promote inflammation and dysregulation of the immune system.

About Neovacs

Listed on Alternext Paris since 2010, Neovacs is today a leading biotechnology company focused on an active immunotherapy technology platform (Kinoids) with applications in autoimmune and/or inflammatory diseases. On the basis of the company's proprietary technology for inducing a polyclonal immune response (covered by five patent families that potentially run until 2032) Neovacs is focusing its clinical development efforts on IFNα-Kinoid, an immunotherapy being developed for the indication of lupus, dermatomyositis and also in preclinical trial for Type 1 diabetes. Neovacs is also conducting preclinical development works on other therapeutic vaccines in the fields of auto-immune diseases, oncology and allergies. The goal of the Kinoid approach is to enable patients to have access to safe treatments with efficacy that is sustained in these life-long diseases. www.neovacs.fr

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