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## Neovacs Announces Positive Data Review from Last IDSMB Review Prior to Final Results of Phase IIb Clinical Trial of IFN $\alpha$ Kinoid in Lupus

### *Final Trial Results Expected in June 2018*

Paris and Boston, February 13<sup>th</sup> 2018, 07:00 am CET - Neovacs (Euronext Growth: ALNEV), a leader in active immunotherapy for the treatment of autoimmune diseases, today announces that it has received a positive data review from the Independent Data and Safety Monitoring Board (IDSMB) related to the ongoing Phase IIb clinical trial of IFN $\alpha$  Kinoid in lupus. This was the last IDSMB data review prior to the final results from this trial.

The IDSMB reviewed the cumulative data from the 185 patients randomized who have received the full administration of IFN $\alpha$  Kinoid vaccine or placebo (ratio 1:1), according to the dosing regimen defined in the study protocol. Following this review of the data concerning tolerance and safety, the IDSMB recommended that Neovacs continue the study without any modification of the protocol.

**Dr. Thérèse Croughs, Chief Medical Officer of Neovacs**, commented: "*We are pleased to have reached this last milestone, which allows us to confirm that the results of this clinical study should be available in June 2018.*"

The IFN $\alpha$  Kinoid Phase IIb trial in lupus is now fully enrolled with 185 patients randomized, and is being conducted in approximately 20 countries across the U.S., Europe, Latin America, Asia, and North Africa. The objective of the study is to evaluate the biological and clinical efficacy of IFN $\alpha$  Kinoid, the most advanced product candidate in Neovacs' development pipeline, in patients with moderate to severe lupus.

#### **About Lupus**

Systemic lupus erythematosus (SLE) or lupus erythematosus is a debilitating, chronic autoimmune disease whose etiology remains unknown. SLE is characterized by a loss of tolerance of self-antigens, with the production of autoantibodies, especially antinuclear antibodies that attack healthy tissues and cause inflammatory reactions in different parts of the body. The disease can affect multiple organs (skin, kidneys, joints, heart, lungs, central nervous system, etc.) and is characterized by heterogeneous clinical signs (skin rashes, arthritis, photosensitivity, nephritis, neurological disorders, anemia, thrombocytopenia, etc.), which vary from one person to another and change during the progression of the disease. Systemic lupus erythematosus affects mostly women.

#### **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 to a carrier protein. 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 pharmacological effects. Several autoimmune and inflammatory diseases (e.g. systemic lupus erythematosus, dermatomyositis, Type 1 diabetes etc.) are characterized by a disorder of cytokines that are found to be produced in excess (ex: IFN $\alpha$ ), promoting inflammation and dysregulation of the immune system.

### **About Neovacs**

Listed on Euronext Growth 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 four patent families that potentially run until 2032) Neovacs is focusing its clinical development efforts on IFN $\alpha$ -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](http://www.neovacs.fr)

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