Neovacs obtains FDA approval

to extend its Phase IIb clinical trial in Lupus to United States

Paris and Boston, April 28th, 2016 – Neovacs (Alternext Paris: ALNEV) a leader in active immunotherapy for the treatment of autoimmune diseases, today announced that the Company has received the approval "Investigational New Drug" (IND), from the Food and Drug Administration (FDA), to extend its ongoing Phase IIb clinical trial of IFNα Kinoid for the treatment of Lupus to the United States.

Miguel Sieler, CEO of Neovacs commented: "*This clearance by the FDA is a real success for Neovacs and will allow us to extend our actual trial to American investigators and patients. The FDA has given this approval within the regulatory time frame which demonstrates the complete and convincing character of our file. Important investigating centres notably in New York, Oklahoma and Miami have been waiting for this authorisation to set up the trial. Therefore the recruitment of patients will start very soon.*"

This Phase IIb trial now FDA approved, is a worldwide multicentric study, randomized versus placebo, initiated in October 2015 in Lupus. Its objective is to evaluate the biological and clinical efficacy of the IFNα Kinoid, the most advanced product of the Neovacs portfolio in patients with a moderate to severe form of Lupus disease. This 18 months trial will now enroll 178 patients in 19 countries throughout Europe, Asia, Latin America, and now the United States.

This approval is an important step for Neovacs. Indeed the high prevalence of Lupus disease in the United States as well as its ethnic diversity, reinforce our clinical development strategy for this therapeutic vaccine. Full Phase IIb results are expected in mid-2017. They will be presented to the relevant health Authorities in Europe (EMA) and in the US (FDA) in order to validate the start into Phase III trial of IFNα Kinoid in Lupus.

About Neovacs Created in 1993, 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 and dermatomyositis. 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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