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Neovacs obtains south korea health authority approval for ind application with IFN α kinoid in lupus

Paris, April 14th, 2016 – NEOVACS (Alternext Paris : ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, today announced that South Korea health authority approved Neovacs's Investigational New Drug application for IFN α Kinoid in phase IIb development in Lupus.

Miguel Sieler, CEO of NEOVACS commented about this trial, now including South Korea : *“The examination of our trial has been particularly detailed and has therefore taken into consideration the innovative character of our technology in the frame of the development of a new therapeutic approach for a rare disease. Indeed the Korean health authorities were very demanding and wanted to analyze and understand clearly the mechanism of action and the preclinical and clinical data obtained so far as well as the different steps of production. This result is now an expression of confidence which is encouraging for the future.”*

Neovacs has indeed signed a licensing and partnering agreement with the Korean company Chong Kun Dan Pharmaceuticals (CKD), leader in South Korea in the field of immunosuppressive drugs. This country is the only one of the OECD where Lupus disease fulfills the requirements to obtain the Orphan disease status. Within this agreement Neovacs will file in a near future for “Orphan Drug Designation”. In case of success of its Phase IIb trial the registration of the product and its launch in the Korean market could as consequence take place without a previous Phase III trial.

Based on these elements having received this IND is of strategic importance for Neovacs and for CKD in order to launch IFN Kinoid in the Korean market.

This actually running Phase IIb trial, randomized, versus placebo and concerning 166 patients, covers more than 100 investigation centers in the world, including now 5 in South Korea. The results of this trial are expected for summer 2017.

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 IFN α -Kinoid, an immunotherapy being developed for the indication of lupus. 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.

All information about Neovacs is available on the website: www.neovacs.fr

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