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NEOVACS RECEIVES FIRST REGULATORY APPROVALS FOR A PHASE IIb TRIAL OF IFNα-KINOID IN LUPUS

IFN-K-002 clinical trial to launch in coming weeks

Paris and Boston, September 1, 2015 – NEOVACS (Alternext Paris: ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, today announced that it has been granted first approvals by regulatory agencies and ethics commitees in several European countries for a Phase IIb clinical trial of IFNα-Kinoid in Systemic Lupus Erythematosus (SLE) or lupus.

The upcoming trial was notably assessed favorably using the Voluntary Harmonization Procedure (VHP) of Europe's Heads of Medicine Agencies, which allows for a harmonized assessement of clinical trials by relevant national health authorities.

Acceptance by competent authorities enables Neovacs to initiate IFN-K-002, a Phase IIb clinical study to assess the biological and clinical efficacy of Neovacs' lead active immunotherapy product candidate IFNα-Kinoid in patients suffering from lupus. Inclusion of first patients is expected to begin in the coming weeks. Approvals from other European, Asian and Latin American countries are expected in the second half of 2015.

Phase IIB trial design for IFN-K-002 in SLE

IFN-K-002 is a double-blind, randomized, placebo-controlled multicentric Phase IIb clinical trial designed to assess the efficacy and safety of IFNα-Kinoid in moderate to severe lupus patients. The study will recruit 166 patients across 19 countries in Europe, Asia and Latin America.

The co-primary endpoints for the trial are biogical efficacy and clinical efficacy nine months after first immunization with IFNα-Kinoid. Biological efficacy is defined as IFNα-signature neutralization, while clinical efficacy will be measured by the BILAG-based[1] Composite Lupus Assessment (BICLA) response.

Timelines for the study

Regulatory and ethics committee approvals pave the way for a rapid initiation of the study IFN-K-002. These centers will begin screening and immunizing patients in the coming weeks. Results of the clinical trial are expected in the first quarter of 2017.

[1] The British Isles Lupus Assessment Group (BILAG) is a validated index to measure lupus disease activity listed in FDA guidance on lupus. See FDA Systemic Lupus Erythematosus working group report at : www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072063.pdf#sthash.qR2f2REj.dpuf

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.

For more information on Neovacs, please visit www.neovacs.fr

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