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Neovacs enrolls the first U.S. Patient in Phase IIb study of IFN α Kinoid for treatment of Systemic Lupus Erythematosus (SLE)

Strong interest from U.S. clinical investigation centers trial

Paris and Boston, November 7th 2016 - Neovacs (Alternext Paris: ALNEV, PEA-eligible SMEs), a leader in active immunotherapy for the treatment of autoimmune diseases, today announced the enrolment of the first U.S. patient in its international phase IIb clinical study of IFN α Kinoid in lupus.

A first clinical center has started to enrol patients in this study, initially planned to include 5 investigation centers. The study has attracted interest from a large number of American sites and autoimmune disease specialists. Due to this high demand, Neovacs will open additional centers, increasing the total number of trial sites to 15.

This Phase IIb trial is part of a randomized, multicentric, international clinical study, initiated in September 2015. The ongoing study is evaluating IFN α Kinoid versus placebo in the treatment of systemic lupus erythematosus (SLE). Its objective is to assess the biological and clinical efficacy of IFN α Kinoid, the most advanced product in Neovacs' pipeline, in patients who have moderate to severe SLE. The trial is planned to include 178 patients in 21 countries in Latin America, Asia, Europe and USA.

Miguel Sieler, CEO of Neovacs declared: "The enthusiasm among U.S. investigators confirms the strong therapeutic interest in our product for the treatment of autoimmune diseases. Our lead drug candidate represents a potentially very interesting option for the treatment of lupus, an area where current therapeutic standards have failed to prove long-term efficacy. This is an area with a significant unmet medical need, and we look forward to continuing the study with the goal of providing a new therapeutic option for patients in need."

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.

In 2014, there were 37,369 patients in France, of which 88% are women. The prevalence is 47 cases per 100,000 people, while the overall annual incidence reached 3.32 cases per 100,000 people, peaking in the female population aged 30 to 39 years (9.11 cases per 100 000 people).

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 (Type 1 diabetes, systemic lupus erythematosus, psoriasis, etc.) are characterized by a disorder of cytokines that are found produced in excess (ex: IFN α). 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 IFN α -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.

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