

PRESS RELEASE • PRESS RELEASE • PRESS RELEASE

## NEOVACS ANNOUNCES THE COMPLETION OF PATIENT ENROLLMENT IN PHASE IIB CLINICAL STUDY OF IFNα Kinoid IN LUPUS

Company Expects the Availability of Results from the Study in Q2 2018

**Paris and Boston, June 20, 2017 – 7:00 AM CET – Neovacs (Alternext Paris: ALNEV),** a leader in active immunotherapies for the treatment of autoimmune diseases, today announced the completion of patient enrollment for its phase IIb clinical study, IFN-K-002, evaluating IFN $\alpha$  Kinoid for the treatment of lupus.

"The completion of enrollment is an important milestone for our IFN Kinoid program and confirms the interest of leading clinicians conducting our trial in this novel therapeutic approach" said **Therese Croughs, Chief Medical Officer of Neovacs.** "We are looking forward to the results from the study in Q2-2018".

Study IFN-K-002 includes 178 patients who have moderate to severe systemic lupus erythematosus (SLE). This worldwide, randomized, multicentre international phase IIb study is evaluating IFN $\alpha$  Kinoid versus placebo and is being conducted under IND<sup>1</sup> in Europe, Asia, North Africa, South America, and the United States. All the patients are being treated and followed up for 9 months for the main study.

Neovacs designed this Phase IIb clinical trial to obtain relevant and meaningful data on:

- **Biological efficacy**: by measuring the decrease of interferon gene signature, one of the primary markers of disease activity.
- Clinical efficacy: by using the BICLA<sup>2</sup> response score at Month 9. This score is one of the end-points validated by health authorities to evaluate the clinical response in lupus clinical studies.

The company has chosen a successful strategy which promotes the recruitment of eligible patients in this phase IIb clinical trial in lupus, a rare and complex disease, with a number of patients worldwide estimated to 5 million<sup>3</sup>.

In order to ensure the validity of the clinical results of this study, Neovacs is taking advice from three expert committees: 1) the independent Data Safety Monitoring Board "iDSMB", whose mission is related to assessing safety, 2) an independent "Adjudication Committee" to evaluate the consistency of the clinical response data to the vaccine-(BICLA), and 3) an internal "Steering Committee" to oversee the conduct of the clinical trial.

<sup>&</sup>lt;sup>1</sup> Neovacs obtains FDA approval to extend its Phase IIb clinical trial in Lupus to United States

http://neovacs.fr/wp-content/uploads/pr-29-04-16.pdf

<sup>&</sup>lt;sup>2</sup> The BILAG-Based Composite Lupus Assessment- BICLA score : Wallace D. Ann Rheum Dis 2014;73:183-190

<sup>&</sup>lt;sup>3</sup> The lupus foundation of America : http://www.lupus.org/

## **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 targeted cytokine to a carrier protein. The intramuscular injection of this Kinoid induces an immune response and stimulates the production of polyclonal antibodies against the targeted cytokines. It is thus possible to block cytokine overproduction and its pharmacological effects. Several autoimmune and inflammatory diseases (lupus, dermatomyositis, Type 1 diabetes ...) are characterized by a disorder of cytokines that are found produced in excess. As an example, the overproduction of IFN $\alpha$  will promote inflammation and dysregulation of the immune system.

## **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 as the disease progresses. Systemic lupus erythematosus affects mostly women.

## **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 $\alpha$ -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, allergies and Type 1 diabetes. 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. <u>www.neovacs.fr</u>

Contacts NEOVACS – Corporate Communication & Investor Relations Charlène Masson +33 (0)1 53 10 93 14 cmasson@neovacs.com

NEWCAP- Press relations Annie-Florence Loyer +33 1 44 71 00 12 / + 33 6 88 20 35 59 afloyer@newcap.fr

Léa Jacquin +33 1 44 71 20 41 / +33 6 58 14 84 66 ljacquin@newcap.fr

LIFESCI ADVISORS- Investor Relations / Financial Communications Chris Maggos +41 79 367 6254 chris@lifesciadvisors.com