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# NEOVACS REPORTS FIRST POSITIVE IMMUNOGENICITY RESULTS FOR IFNα KINOID IN MODEL OF TYPE 1 DIABETES

# THE SCIENTIFIC ADVISORY BOARD RECOMMENDS IFN $\alpha$ KINOID DEVELOPMENT FOR TYPE 1

## DIABETES

**Paris and Boston, January 25, 2017 – Neovacs (Alternext Paris: ALNEV),** a leader in active immunotherapies for the treatment of autoimmune diseases, today announced the recommendation of its Scientific Advisory Board to extend the development of IFN Kinoid to a new indication, Type 1 Diabetes, with the objectives of obtaining preclinical proof of concept in 2017 and initiating clinical development for this program in the first half of 2018. IFN Kinoid is also currently in Phase IIb testing for treatment of Lupus and recently received U.S. FDA Fast Track designation in this indication.

"Based on the immunogenicity results obtained in relevant preclinical model (NOD-Mice<sup>1</sup>) and our Phase I/IIa data in Lupus, showing a reduction in IFN alpha signature after IFN Kinoid treatment, we believe this product also has significant potential in the treatment of Type 1 Diabetes, in addition to Lupus. Further Data from preclinical proof of concept study in Type 1 diabetes – expected in summer 2017 – will be an important value creating milestone for Neovacs," said **Miguel Sieler**, Chief Executive Officer. "I wish to thank the distinguished members of our Scientific Advisory Board for their work and continuous support."

The recommendation issued by the Company's scientific advisory Board is based on achieving a high level of immunogenicity after IFN Kinoid administration, in a relevant preclinical model of Type 1 diabetes. Indeed, Neovacs observed in treated NOD-Mice, a significant level of anti-interferon Alpha neutralizing antibodies. This study was conducted by Neovacs in collaboration with **Doctor Agnès Lehuen and Professor Christian Boitard** from the department of Immunology of Diabetes at the Hospital Cochin in Paris<sup>2</sup>.

The rationale for pursuing Type 1 diabetes is further supported by well-established data showing that overexpression of IFN $\alpha$  plays a key role in this autoimmune disease, as also observed in lupus and dermatomyositis. In its completed Phase I/IIa study with IFN Kinoid in Lupus, Neovacs demonstrated that IFN Kinoid generated long-lasting anti-interferon polyclonal antibodies that had biological activity capable of neutralizing the IFN signature in humans suffering from Lupus<sup>3</sup>. In addition, a favorable safety profile was observed.

<sup>&</sup>lt;sup>1</sup> Non-Obese diabetic-Mice

<sup>&</sup>lt;sup>2</sup> Press Release published on October 12th, 2016: Neovacs signs a cooperation agreement with the Department

Immunology of Diabetes at the reputed Hospital Cochin in Paris. To collaborate on development of new diabetes treatment using Neovacs' Kinoid Technology

<sup>&</sup>lt;sup>3</sup> Lauwerys Arthritis&Rheum 2013 and Ducreux 2016 Rheumatology

## <u>Neovacs' Scientific Advisor Board was composed of world-renowned immunologists and diabetes</u> <u>experts:</u>

- Prof. Jacques Banchereau, Chairman of the Scientific Advisory Board of Neovacs, Director of Immunological Science at the Jackson Laboratory for Genomic Medicine, Farmington, Conn. USA
- Prof. Christian Boitard, MD, PUPH, Immunology of diabetes Institute Cochin- University Paris Descartes Paris
- Prof. Michael Clare-Salzler, MD Professor and Chair of the department of pathology, University of Florida, Gainesville, FL
- Prof. Kevan Herold, MD Professor of immunology and internal medicine, Yale University, New Haven, CT
- Dr. Agnes Lehuen, Director of research, CNRS, Immunology of diabetes Institute Cochin-University Paris Descartes Paris
- Prof. Virginia Pascual, MD Director, Center for Inflammation and genomics, Baylor Institute for Immunology Research Dallas, Texas

The data obtained with IFN Kinoid in preclinical and clinical studies in Lupus conducted by Neovacs, will also be used for clinical development in Type 1 diabetes. No additional toxicity study will be needed before initiating a clinical trial, thus accelerating the development timeline for this indication.

### About Type 1 Diabetes

Type 1 Diabetes is an autoimmune disease which is foreseen to affect 25 million people in the world by the year 2020 with growing incidence worldwide (+3%pa). *Source WHO*. This disease may cause severe and even life threatening complications and has no curative treatment. Patients have to monitor their glycaemia throughout the day and are treated with multiple insulin injections over their lifetime.

#### **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 $\alpha$ ). 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 $\alpha$ -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. www.neovacs.fr

Contacts NEOVACS – Corporate Communication & Investor Relations Charlène Masson +33 1 53 10 93 14 <a href="mailto:cmasson@neovacs.com">cmasson@neovacs.com</a>

LIFESCI ADVISORS- Investor Relations / Financial Communications Chris Maggos <u>chris@lifesciadvisors.com</u>

+41 79 367 6254