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NEOVACS ANNOUNCES TOP LINE PHASE IIB CLINICAL TRIAL RESULTS OF TNF-KINOID IN RHEUMATOID ARTHRITIS AND UPDATE ON CLINICAL PROGRAMS

- **Phase Iib clinical trial of TNF-Kinoid in Rheumatoid Arthritis confirmed the good safety profile as well as antibody production, but failed to meet efficacy endpoints. Further evaluation is ongoing.**
- **Clinical studies of IFN α -Kinoid in lupus to be initiated mid 2015 in Europe, Latin America and Asia, and early 2016 in the U.S.; Preclinical development programs to proceed as planned**
- **Financial agreement with Kepler Cheuvreux of up to €20 million extends operating capital beyond 2015**

Paris, December 16, 2014 – NEOVACS (Alternext Paris: ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, today announced top line data on the Phase Iib clinical trial of TNF-Kinoid in Rheumatoid Arthritis (RA).

This trial confirmed the immunogenicity and good tolerance of TNF-Kinoid with no safety issues, but did not meet its primary efficacy endpoint.

“We are disappointed that our TNF-Kinoid Phase Iib study did not have a positive outcome, given the potential benefits that this new approach would have brought to patients suffering from RA. We are in the process of analyzing the data in depth to understand the lack of clinical efficacy for TNF-Kinoid in this trial and to discuss potential next steps with Neovacs Scientific Advisory Board and with our prospective partners. These findings will determine future developments of TNF-Kinoid within our portfolio,” said Miguel Sieler, Neovacs CEO.

“As we analyze these data, we will focus our research efforts and resources on the clinical development of IFN α -Kinoid in lupus, a disease that affects over six million people worldwide, and for which no fully effective biological treatment currently exists.”

TNF-Kinoid Phase IIb trial in Rheumatoid Arthritis fails to meet primary endpoint

In 2014, Neovacs completed a randomized, double-blind, placebo-controlled, multicenter 140-patients Phase IIb clinical trial of TNF-Kinoid in RA. The co-primary endpoints for the study were based on the DAS28-CRP and ACR 20 scores – measures commonly used in clinical trials for RA.

The study confirmed the safety and tolerability of the product. An independent Data Safety and Monitoring Board had previously issued positive assessments on safety in January and March 2014.

All patients, except one, showed a significant immune response, producing anti-TNF binding antibodies.

However, the patients did not produce neutralizing antibodies, which is the most likely hypothesis to explain the absence of a statistically significant clinical response. Neovacs intends to further analyze these s top line data to determine the reason for the absence of a significant clinical response.

“The findings of the TNF-Kinoid study in RA and our continued work with this program have allowed us to make significant progress on our understanding of active immunotherapies for the treatment of auto-immune diseases. The clinical results of this study do not preclude further development of the Kinoid platform, in particular IFN α -Kinoid in lupus. Neovacs’ program in lupus is highly promising from a scientific perspective, based on the existing clinical and preclinical findings which show strong immune response with neutralizing antibodies, as well as an improvement of lupus related biomarkers,” said Professor Jacques Banchereau, Ph.D, chairman of Neovacs’ scientific advisory board.

Two IFN α -Kinoid clinical trials to start in 2015-2016

During 2015, depending on the date of regulatory approvals, a Phase IIb clinical trial will be initiated in Europe, Latin America and Asia. In addition, a Phase IIa study is planned to start in the U.S. during early 2016 in the same indication.

Neovacs presented data in June 2014¹ demonstrating that self-polyclonal antibodies induced by immunization of lupus patients with IFN α -Kinoid neutralized all IFN α subtypes. Neovacs’ IFN α -Kinoid is the only treatment able to induce polyclonal antibodies that effectively and specifically neutralize all subtypes of IFN α present in excess in lupus.

“The specific neutralization of the 13 subtypes of IFN α overexpressed in lupus differentiates our therapeutic approach. Based on what has been published to date, the Kinoid is the first treatment to achieve this complete and specific neutralization. These results confirm that IFN α -Kinoid has the potential to become a breakthrough treatment in lupus” said Pierre Vandepapelière, M.D., Ph.D., Neovacs Chief Medical Officer.

Financing of Neovacs ensured beyond 2015

As announced with the publication of Half Year 2014 results, financing of Neovacs is ensured until Q2 2015. This cash runway has been significantly extended with the up to €20 million financing agreement put in place with Kepler Cheuvreux.

¹ European League Against Rheumatism Annual Meeting, EULAR 14-SCIE-3726. Abstract available at <https://b-com.mci-group.com/AbstractList/EULAR2014.aspx>

About Neovacs

Neovacs is a 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 run potentially until 2032), Neovacs is focusing its development efforts on two active immunotherapies: TNF-Kinoid is being developed for the treatment of TNF-mediated autoimmune diseases such as rheumatoid arthritis and Crohn's disease, whereas IFN α -Kinoid is being developed for the indication of lupus. 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, visit www.neovacs.fr

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