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NEOVACS ANNOUNCES THE RESULTS OF ITS PHASE IIB STUDY FOR IFNα KINOID IN THE TREATMENT OF LUPUS WHICH ALLOWS TO PROCEED WITH THE CLINICAL DEVELOPMENT INTO PHASE III

THE BIOLOGICAL OBJECTIVE AND THREE OUT OF FOUR CLINICAL OBJECTIVES WERE MET:

- **Highly statistically significant efficacy in reduction of interferon signature**
- **Lack of statistically significant clinical efficacy measured by BICLA[1] score**
- **Statistical trend on clinical efficacy measured by SRI-4[2] with reduction of steroid ≤5mg/day**
- **Statistically significant clinical efficacy on the LLDAS[3] score**
- **Favorable safety profile of IFNα Kinoid treatment**

Paris and Boston, July 3, 2018 - 7:00 am CEST - Neovacs (Euronext Growth Paris: ALNEV), a leader in active immunotherapy for the treatment of autoimmune diseases, today announces the results of its Phase IIb clinical trial of IFNα Kinoid in patients with moderate to severe lupus (SLE).

The results show a very statistically significant **biological efficacy** of IFNα Kinoid ($p < 0.0001$), measured by the decrease of the interferon signature at week 36 of the study. The clinical response in patients treated with IFNα Kinoid vs those treated with placebo measured by the **BICLA score** at week 36, did not achieve a statistical trend as defined in the primary objectives of the study.

*"**It is important to note the very marked effect of IFNα Kinoid on the LLDAS score, of which one of the 5 criteria is the reduction of steroid use**,"* stressed Professor Frédéric Houssiau, Scientific Chairman of the study, Rheumatology Department, Saint-Luc Clinical Universities, Brussels, Belgium. *It suggests that **one must take into account the reduction of steroid therapy**, an important goal of treatment. This study demonstrates, once again, the difficulties in choosing the primary clinical endpoint in SLE."*

The main secondary endpoints for assessing **clinical efficacy** were:

- **SRI-4 with steroid reduction ≤ 5 mg/day**
- **LLDAS (Lupus Low Disease Activity Score)**

Measured in week 36, SRI-4 with a reduction of steroid to ≤5mg/day showed a statistical trend of 54.4% for treated patients vs. 39% in those treated with placebo ($p = 0.07$) and the LLDAS a statistically significant effect of 52.9% vs. 29.8% ($p = 0.002$). Both point in favor of IFNα Kinoid treatment, which coupled **with a major reduction in steroid is an important therapeutic step forward**.

IFNα Kinoid was well tolerated and serious adverse events were reported more frequently in the placebo group (12.9%) compared to the IFNα Kinoid treated group (6.6%).

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[1] *BILAG-Based Composite Lupus Assessment score*

[2] *Systemic Lupus Erythematosus Responder Index-4 with a reduction at ≤5mg/day level of glucocorticoids ≤5mg/day*

[3] *Lupus Low Disease Activity State*

"*These results of clinical efficacy, in particular on two reference indices* ***(SRI-4 with steroid reduction to ≤ 5 mg/day and LLDAS****) which have been validated by international health authorities or medical community,* ***authorise the further clinical development with these scores into phase III***," said Thérèse Croughs MD, Chief Medical Officer of Neovacs. "*We would like to express our thanks to the patients, the investigators and all those who contributed to this important Phase IIb trial of our therapeutic vaccine in lupus*."

This double blind, randomized, placebo-controlled, multi-center, Phase IIb study enrolled 185 patients in Europe, Asia, the United States, North Africa, and Latin America with moderate to severe lupus. The primary endpoints for the trial were biological efficacy and clinical efficacy nine months after the first treatment with IFNα Kinoid. Patients were randomized to receive either IFNα Kinoid or placebo intramuscular 5 times: days 1, 7, and 28 and then at 3 and 6 months. Patients also received standard treatment with antimalarials, immunosuppressants and / or steroids, the latest were gradually decreased to a dose ≤5 mg of prednisolone equivalent / day by 24 weeks and remained stable until the 36th week. At the end of this primary evaluation period, patients entered a 5-year follow-up period to assess the safety as well as the long-term biological and clinical efficacy of IFNα Kinoid.

"*We are very pleased with these results that will enable us to move into phase III within a partnering to be finalised,* ***in line with the objectives announced previously***," said Miguel Sieler Chief Executive Officer of Neovacs, adding, "***We have achieved 4 major objectives in a complex autoimmune disease****. These results confirm the relevance of our innovative therapeutic approach and strengthen the potential of Kinoid treatment*. "

Neovacs plans to submit the full results of this study and present them at a future international scientific congress.

The U.S. Food and Drug Administration has already granted Fast Track Status for IFNα Kinoid in lupus to Neovacs.

Neovacs will hold a Webcast conference call today at 10:00 am CEST, log in via the following link:
https://channel.royalcast.com/webcast/neovacsfr/20180703_2/

For more information, visit this phase IIb clinical study with IFNα Kinoid in the treatment of lupus: www.clinicaltrial.gov. (Identifier: NCT02665364)

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.

About IFNα Kinoide

Neovacs anti-IFNα therapy consists of patient immunization using Interferon α (IFNα) kinoid (IFNα Kinoid). IFNα Kinoid is a heterocomplex consisting of an inactivated IFNα coupled to a T-helper stimulating carrier protein, Keyhole Limpet Hemocyanin (KLH). IFN-K is emulsified with Montanide™ oily adjuvant that non-specifically stimulates cell-mediated immune (CMI) responses to antigens.

IFNα Kinoid elicits the production of neutralizing polyclonal antibodies directed against the excess IFNα, thus blocking its ability to activate the inflammatory cascade. The generation of polyclonal neutralizing antibodies against IFNα following the administration of IFNα Kinoid is relevant to diseases mediated by IFNα over-production, such as Systemic Lupus Erythematosus (SLE), Dermatomyositis (DM), Type I Diabetes (T1D) and Sjögren's Syndrome (SS).

About Neovacs

Listed on Euronext Growth 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 four 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, 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 autoimmune 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

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