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# NEOVACS ANNOUNCES THE FULL RESULTS OF ITS PHASE IIb CLINICAL STUDY OF IFNα KINOID IN LUPUS, PRESENTED AT THE 13th INTERNATIONAL LUPUS CONGRESS 2019

**Paris and Boston, April 9, 2019, 7:30 am CEST – NEOVACS (Euronext Growth Paris: ALNEV)** leader in active immunotherapy for the treatment of auto-immune and inflammatory diseases, announced that the full results of the phase IIb clinical study were presented on April 6, 2019, by Prof. Frédéric Houssiau, MD, PhD, Vice-Rector of the Faculty of Health Sciences at UCL (*Université Catholique de Louvain*), Brussels, Belgium,[1] and chairman of the clinical study, at the first plenary of the international congress on Systemic Lupus Erythematosus, LUPUS 2019 (San Francisco, 5-8 April), during an oral session entitled: "*IFN Kinoid in Systemic Lupus Erythematosus (SLE): Results from a Phase IIb, Randomized, Placebo-Controlled Study* [2]".

**The results confirmed that treatment with IFN-alpha Kinoid induced a strong immune response**: 91.4% of treated patients produce neutralising polyclonal antibodies against interferon alpha.

**Prof. Frédéric Houssiau commented:** *"**A significant biological effect on the interferon signature** was observed in treated patients during the phase IIb study of IFNα Kinoid in lupus. Although the clinical response was not based on a modification of the BICLA score[3] at 36 weeks,* encouraging clinical results were *seen on the SRI score (4), combined with corticosteroid reduction, as well as a **statistically significant clinical result on the LLDAS endpoint."*** [4]

*"According to the world's lupus experts, this LLDAS endpoint may become the main criteria to assess disease activity and response to treatment when submitting applications to regulatory agencies. In addition, this study showed a reduction of corticosteroid therapy, which may eventually lead to a major breakthrough, as it could improve the patients' quality of life considerably by eliminating the adverse effects of corticosteroids*," continued Prof. Frédéric Houssiau.

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[1] Prof. Frédéric Houssiau, MD, PhD, Vice-Rector of the Faculty of Health Sciences at UCL (Université Catholique de Louvain), Brussels, Belgium, and tenured professor at UCL,[1] and formerly Head of the Department of Rheumatology of the St-Luc University Teaching Hospital (Brussels, Belgium), and founding member of the lupus research network.

[2] The abstract presented is available on the Company's website: http://www.neovacs.fr/en/

[3] BICLA: BILAG-based Composite Lupus Assessment

[4] LLDAS: Lupus Low Disease Activity State

**This study also showed:**

- A statistical trend observed on the SRI-4 clinical score,[5] with corticosteroid reduction to ≤5 or 7.5 mg/day (p=0.07), which became **statistically significant (p=0.04) in the subgroup of patients who developed neutralising antibodies against interferon alpha;**

- **A statistically significant clinical response (p=0.0022**) **based on the LLDAS score**, with 52.9% responders in the treated group, versus 29.8% in the placebo group, i.e. a 23% difference;

- **A marked difference in corticosteroid intake**, i.e. 7.1 mg in the placebo group, versus 5.4 mg in the group of patients treated with IFNα Kinoid, at 36 weeks;

- **A statistical trend on the improvement of fatigue in patients treated with IFN-alpha Kinoid (p=0.068).** Fatigue is frequently reported in most chronic conditions. It affects almost 9 in 10 lupus patients. When lupus is active, fatigue is directly associated with the disease;

- **Good tolerance of IFNα Kinoid.** Serious adverse effects were more frequent in the placebo group (13%) than in the group treated with IFN-K (7%). Moreover, frequency and severity of non-serious adverse events were not different in both groups. The main adverse effects reported during the study were mostly related to the disease and to a local reaction at the injection site. The treatment with IFN-alpha Kinoid did not modify or worsen the risk of infection associated with lupus.

All these highly encouraging results must be assessed further in a phase III clinical program.

**About the 13th international lupus congress**

The 13th International Congress on Systemic Lupus Erythematosus (LUPUS 2019) is proud to invite you to San Francisco, California USA, April 5-8, 2019. This exciting meeting, *"LUPUS: Gateway to the Future"* will highlight advances and insights from recent SLE research into the causes and outcomes of SLE, explore the promise of implementing a personalized approach to diagnosis, prognosis, and treatment, and provide a forum to hear exciting and innovative research from a new generation of investigators. The Congress will span the disciplines dedicated to improving outcomes in SLE, from basic and translational science through epidemiology and outcomes research.

http://lupus2019sf.org/

[5] SRI: Composite Systemic Lupus Erythematosus (SLE) Responder Index 4 with corticosteroid reduction to ≤5mg/day.

**About the Phase IIb study with IFNα Kinoid in the treatment of 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.

**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 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**


**Néovacs**
**Corporate Communication**
**& Investor Relations**
**Charlène Masson**
+33 1 53 10 93 00
cmasson@neovacs.com

**Press Relations – NewCap**
**Annie-Florence Loyer**
+33 (0)6 88 20 35 59
+33 (0)1 44 71 00 12
afloyer@newcap.fr
**Léa Jacquin**
Tel : +33(0)1 44 71 20 41
ljacquin@newcap.fr

**Orphéon Finance**
**Financial Communication and Investor Relations**
**James Palmer**
+33 7 60 92 77 74
j.palmer@orpheonfinance.com