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## NEOVACS REPORTS FULL-YEAR 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- KEY OPINION LEADERS VALIDATE THE THERAPEUTIC POTENTIAL OF IFN $\alpha$  KINOID IN LUPUS TREATMENT FOLLOWING THE RESULTS OF THE PHASE IIB CLINICAL STUDY
- SUCCESSFUL IN VIVO PROOF OF CONCEPT FOR ITS IL-4 / IL-13 KINOID A NEW THERAPEUTIC VACCINE TO TREAT MITE-INDUCED ASTHMA
- PATENT REGISTERED IN EUROPE AND THE U.S. FOR IL-4 / IL-13 KINOID, CANDIDATE VACCINE IN THE TREATMENT OF ALLERGIES
- FINANCIAL VISIBILITY BEYOND 12 MONTHS
- NET LOSS REDUCTION BY € 4M

**Paris, March 25, 2019, 7:30 am CET – NEOVACS (Euronext Growth Paris: ALNEV)**, a leader in active immunotherapies for the treatment of autoimmune diseases, provides today a corporate update and reports its financial results for the 12 months ended December 31, 2018, as approved by the Company's Board of Directors on March 22, 2019.

**Miguel Sieler, CEO of Neovacs**, said: " 2018 was marked by significant progress in our clinical and preclinical development programs. The results of the lupus phase IIB study<sup>1</sup> have led international scientific experts to reaffirm the therapeutic potential of our flagship product, IFN $\alpha$  kinoid, to treat lupus. At the same time, we announced very promising pre-clinical results with our product IL-4 / IL-13 Kinoid, a therapeutic vaccine candidate for allergies. This work has been supported by significant investments and mobilized our teams for the success of future milestones for society."

<sup>1</sup> Press Release published July 3<sup>rd</sup> 2018: Neovacs announces the results of its phase IIB study for IFN $\alpha$  kinoid in the treatment of lupus which allows to proceed with the clinical development into phase III

## KEY 2018 ACHIEVEMENTS

**The results of its Phase IIb study for IFN $\alpha$  kinoid in the treatment of lupus which permitted to proceed with the clinical development towards 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 BICLA1 score
- Statistical trend on clinical efficacy measured by SRI-42 with reduction of steroid  $\leq 5\text{mg/day}$
- Statistically significant clinical efficacy on the LLDAS3 score
- Favorable safety profile of IFN $\alpha$  Kinoid treatment

**Biosense Global exercised its option as stipulated in the license agreement signed on February 2017 for a global value of up to 65 million euros.** Biosense Global acquired exclusive rights to develop and commercialize IFN $\alpha$  Kinoid for the treatment of Lupus in China

**Continuation of the development of the IFN $\alpha$  kinoid in South Korea with our partner Chong Kun Dang (CKD) pharmaceuticals** on the basis of the licensing agreement signed in December 2015, for a potential overall value of 5M€. This agreement covers the development and the commercialization of IFN $\alpha$  Kinoid in South Korea for Lupus and Dermatomyositis indications.

Within this agreement both partners have agreed to prepare the filing for an “ODD” in South Korea, based on the results of the Phase IIb trial in Lupus with IFN $\alpha$  Kinoid.

Neovacs had already received in 2016 an “Investigational New Drug” (IND) of South Korean Health authorities to include 5 investigational centers in its global Phase IIb trial for IFN $\alpha$  Kinoid. Neovacs was able therefore to gain the support of Korean Opinion Leaders in Lupus for its innovative therapeutic approach and to include Korean patients in the study.

**Neovacs and Centurion Pharma continue their collaboration in Lupus based on the results of the Phase IIb trial with IFN $\alpha$  Kinoid** Through this contract Centurion Pharma has acquired an exclusive commercial license for Turkey.

**Successful in vivo Proof of Concept for its IL-4 / IL-13 Kinoid a new Therapeutic Vaccine to treat Mite-induced Asthma** The IL-4 / IL-13 Kinoid, a therapeutic vaccine from Neovacs' innovative technology is designed to target allergic diseases such as asthma and food allergies. The results obtained in this preclinical study show that the vaccine is able to inhibit bronchoconstriction, and therefore to restore breathing capacity.

**Financing secured from the ANR – The French National Research Agency – to develop the IL-4/IL-13 kinoid as an allergy treatment** The AllergyVACS project aims to formulate Kinoid vaccines that neutralize the IL-4 and IL-13 cytokines, providing long-term protection against allergies. Neovacs issued a press release in December 2018 and filed a patent with the relevant authorities after obtaining preclinical proof of concept in an asthma model

**Filing of a patent in Europe and the United States for its therapeutic vaccine candidate kinoid IL-4 / IL-13 for the treatment of allergies**

**Strengthened of intellectual property in U.S, Europe, Russia and Japan, as part of Neovacs' international development strategy, its patent: “Method for treating Interferon alpha related**

conditions”, has been extended to cover U.S, Europe, Russia, Japan and Hong Kong from previously being awarded in China and Mexico. This reinforces the intellectual property portfolio of the IFN $\alpha$  Kinoid vaccine until at least 2032, as well as the global protection of its technology platform and its applications.

#### **Appointment of the Clinical Advisory board to design the Phase III study for IFN-k in lupus**

This CAB under the Chairmanship of Pr Frédéric Houssiau was held in Paris on the 11th of February 2019.

#### **Appointments to the Executive Committee**

Vincent Serra, PhD is appointed Chief Scientific Officer.

Valerie Salentey, Pharm D, is appointed Head of Regulatory Affairs

## **FULL-YEAR 2018 FINANCIAL RESULTS**

### *Summary financial information*

In 000's Euros	December 31 <sup>st</sup> 2018	December 31 <sup>st</sup> 2017
<b>Revenues</b>	145	834
<b>Operating Costs</b>	13 225	19,163
<i>of which R&amp;D</i>	<i>10 591</i>	<i>16 475</i>
<b>Operating income/(loss)</b>	<b>(13,080)</b>	<b>(18,329)</b>
<b>Financial results</b>	(473)	(636)
<b>Operating income before tax</b>	(13,552)	(18,965)
<b>Non recurring result</b>	(3)	105
<b>Research tax credit</b>	<b>(2,775)</b>	<b>(4,022)</b>
<b>Net income/(loss)</b>	<b>(10,780)</b>	<b>(14,838)</b>

### **KEY ELEMENTS OF THE FULL YEAR 2018 RESULTS**

For the year ended December 31<sup>st</sup> 2018, Néovacs recorded an operating loss of €13.1 million compared to a loss of €18.3 million in 2017. This reduction in the operating loss (+€5.2m) is in line with the development plan reflecting a 31% drop in operating costs following completion of the Phase IIb clinical study for which the results were announced on July 3<sup>rd</sup> 2018. Indeed, R&D expenditure of €10.6 million (which represents 80% of operating costs) were for the most part (62%) directed towards clinical development costs.

In parallel, the company continued to maintain strict control over SG&A costs. Administrative expenditure amounted to €2.6 million representing 20% of operating costs and headcount remained stable for the year at 25.

Financial results showed a small improvement (€0.2 m) as a result of amortization of early bond redemption premiums.

At the net income level, Néovacs reduced the net loss by €4.1 million to €10.8 million compared to a loss of €14.9 million in 2017.



## THE FINANCIAL SITUATION AS AT DECEMBER 31<sup>ST</sup> 2018

As at December 31<sup>st</sup>, 2018, the cash position amounted to €1.4 million compared to €5.1 million at the end of 2017. The cash consumption in 2018 was essentially attributable to the funding of the completion of key R&D programs such as delivering the results for the main Phase IIb study and the in vivo Proof of Concept for IL-4 / IL-13 Kinoid to treat asthma.

Since the beginning of 2019 however, the financial structure has been significantly reinforced by the:

- €2 million received from the drawdown against the equity financing line provided by Kepler Cheuvreux (Equity Line 3)
- €10 million convertible bond issuance spread over 24 months (Ornane – bond convertible into new or existing shares or refundable in cash) without warrants.

Based on R&D cost forecast, the company is financed for the next 12 months. These will focus on financing the progress of the patients already treated as part of the 5 year follow up program included in the protocol for the Phase IIb study and the potentially value creating Kinoid preclinical studies for Type 1 diabetes and allergies.

The full annual financial report for 2018 will be published and filed with the market authorities AMF on April 30<sup>th</sup> 2019. It will be available on the company's website ([www.neovacs.fr](http://www.neovacs.fr))

### About Neovacs

Listed on Euronext Growth 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 four 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. [www.neovacs.fr](http://www.neovacs.fr)

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