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# NEOVACS ANNOUNCES ITS 2019 HALF-YEAR RESULTS

**Paris and Boston, 2nd October, 2019—9:30 p.m. CEST—NEOVACS (Euronext Paris: ALNEV, eligible for PEA-PME),** a leading provider of therapeutic vaccines for the treatment of autoimmune diseases, announced today its 2019 half-year results for the period ending on 30th June 2019, approved by the Board of Directors on 2nd October 2019.

- **Results for the first half of 2019:**
  - Cash balance improved to €3.5m compared to 31/12/18
  - Reduction of net loss by 38%
  - Reduction in monthly spending by 40%
- **Focusing the strategy:**
  - IFNα KINOID Programme in lupus
  - Preclinical programme with IL-4/IL-13 KINOID in allergies
- **Financing:**
  - The drawdown of the 3rd ORNANE tranche representing a nominal amount of €1.25M and funding of €0.7M under the ORNANE programme
  - Funding of activities until the first quarter of 2020 and additional financing capacity of €6.5 million under the conditions of the ORNANE programme
  - Reduction of the share capital reducing the nominal value to €0.05 per share

Vincent Serra, Chief Executive Officer of Neovacs, announced: *"We will focus exclusively on two key priorities: adoption of the Low Lupus Disease Activity State (LLDAS) by health authorities and the value creation of all KINOID technology results both in lupus and preclinical allergy".*

Neovacs will hold an audio conference ( French only) call 3rd October, 2019 at 5:45 pm CEST, dial in numbers will be available via the following link:
https://channel.royalcast.com/webcast/neovacsfr/20191003_2/

# 1) KEY HIGHLIGHTS H1 2019

## A. IFNα KINOID CLINICAL PROGRAMME IN LUPUS

### PRESENTATION OF THE FULL RESULTS OF THE PHASE IIB STUDY OF IFNA KINOID FOR TREATING LUPUS: TO KEY OPINION LEADERS SPECIALIZED IN AUTO IMMUNE DISEASES AND RHUMATOLOGY (6th APRIL, 2019, SAN FRANCISCO, USA)

- A polyclonal immune response to interferon α obtained in 91% of patients treated with IFNα KINOID associated with a statistically significant decrease in interferon characteristics
- Statistically significant clinical efficacy on the LLDAS criterion
- Good treatment tolerance

### APPOINTMENT OF Dr VIRGINIA PASCUAL AS MEDICAL AND SCIENTIFIC ADVISOR

Neovacs appointed Dr Virginia Pascual as Medical and Scientific Advisor in June 2019, replacing Dr Thérèse Croughs. Dr Virginia Pascual is the Director and Founder of Gale and Ira Drukier, Institute of Children's Health, Weill Cornell Medicine, New York, U.S. She has received numerous awards, notably from the National Institute of Allergy and Infectious Diseases, as well as the Lupus Insight Prize for her research.

### AGREEMENT WITH BIOSYN GmbH TO BROADEN ITS SUPPLY IN KEYHOLE LIMPET HEMOCYANIN (KLH)

Neovacs has approved the KLH protein produced by biosyn GmbH to meet its development needs for the IFNα Kinoïd vaccine. Following the acquisition of Stellar Biotechnologies by Edessa Biotech Neostell has been liquidated. This has neither a financial nor operational impact on Neovacs.

## B. PRECLINICAL PROGRAMME WITH IL-4/IL-13 KINOID IN ALLERGIES:

### THE FRENCH AGENCY FOR RESEARCH (ANR) HAS PROVIDED THE FIRST TRANCHE OF THE SUBSIDY FOR IL-4/IL-13 KINOID IN ALLERGIES PROGRAMME

The AllergyVACS project agreement signed between Neovacs and ANR covers an overall grant of €702,000, to be shared between Neovacs and the project's academic partners: INSERM, the *département Immunologie et Allergie de l'Institut Pasteur* (Immunology and Allergy Department of the Institut Pasteur), led by Dr Pierre Bruhns and Dr Laurent Reber's Toulouse Purpan physiopathology centre. This grant will be exclusively dedicated to funding the AllergyVACS preclinical programme.

### THE PRECLINICAL RESULTS OF THE THERAPEUTIC VACCINE CANDIDATE IL-4/IL-13 KINOÏE WERE PRESENTED AT THE FOLLOWING SCIENTIFIC CONFERENCES:

"*Since the beginning of 2019, the largest scientific congresses in the field have selected Neovacs to present the advances of its IL-4 / IL-13 KINOID vaccine in allergies*", states Dr Laurent Reber, from the Antibodies in Therapy and Pathology research unit of the Immunology department at the Pasteur Institute, on these results.

**- Keystone Allergy Congress** — 24th–27th March 2019 — Tahoe, USA

**- The "Antibodies and Complement 2019" Conference** — 20th– 25th May 2019 in Girona (Spain)

**- The European Academy of Allergy and Clinical Immunology conference, "EAACI 2019"** — 1st–5th June 2019 in Lisbon (Portugal)

**- The European Respiratory Society (ERS) international conference** — 28th September to 2nd October 2019 in Madrid (Spain)

This work, carried out in collaboration with the teams at the Institut Pasteur and Purpan (Dr Laurent Reber and Dr Pierre Bruhns), made it possible to demonstrate in a model representing allergic asthma that treatment with IL-4/IL-13 Kinoïd induces the production of polyclonal antibodies neutralising the two targeted cytokines IL-4 and IL-13, factors in the development of respiratory allergies, thus avoiding the emergence of any symptoms.

## 2) PRIORITIES FOR 2019/2020

### IFNα KINOID CLINICAL PROGRAMME IN LUPUS

Following the results obtained in the clinical phase IIb in lupus, Neovacs continues to pursue the preparation of the clinical development programme.

#### ADOPTION OF LLDAS AS THE PRIMARY ENDPOINT FOR A PHASE III CLINICAL STUDY

Based on the statistically significant result of IFNα KinoId obtained with LLDAS in Phase IIb and the approval of the LLDAS approach by the scientific community[1], Néovacs is currently consulting the *Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM)* (French National Agency for the Safety of Medicines and Health Products) on the adoption of LLDAS as a primary criterion for Lupus Phase III. The conclusions are expected in the first quarter of 2020. Consultations with the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) will be scheduled in a second phase.

Following the preliminary ODD adoption, conducted by CKD and Neovacs, the Korean health authorities (MFDS) have not yet selected LLDAS as a viable clinical evaluation criterion; the Orphan Drug Designation status request is therefore suspended.

#### LUPUS PARTNER

The company reaffirms is willingness to find a partner to continue its lupus clinical programme with IFNα Kinoïd in lupus given the level of funding required.

Acceptance of LLDAS as the main evaluation criteria for a phase III study is one of the key elements required for a partnership agreement.

### PRECLINICAL PROGRAMME WITH IL-4/IL-13 KINOID IN ALLERGIES:

Following preclinical results demonstrating the efficacy of prophylaxis in asthma, therapeutic model studies are currently being finalised, which are leading to advances in the product's development. These results will be submitted in Q4 2019 in a peer-reviewed scientific journal.

Neovacs has been contacted to extend this development to animal health, particularly in the treatment of atopic dermatitis in dogs. The Company is currently considering this opportunity.

[1] Golder V, et al. The Lancet Rheumatology (2019).

## 2) 2019 HALF-YEAR FINANCIAL RESULTS

*Summary of financial information*

| *€K* | 30-June-19 | 30-June-18 |
|---|---|---|
| **Operating income** | **264** | **19** |
| **Operating expenses** | **4883** | **6640** |
| *Of which R&D expenditure* | *3359* | *5161* |
| **Operating result** | **-4619** | **-6621** |
| **Financial result** | -61 | -582 |
| **Current result before taxes** | -4681 | -7203 |
| **Exceptional result** | -115 | -429 |
| **Income tax expense** | **1044** | **1535** |
| **Net income** | **-3752** | **-6096** |

### KEY POINTS OF THE 2019 HALF-YEAR RESULTS

- The Company reduced its net loss by 38% in the first half of 2019: -€3.8m compared to -€6.1m by 30th June 2018.
- Thanks to an operating grant received from the ANR and an additional payment made by Centurion, the Company generated operating income of €264k.
- In line with progress of the Company's various clinical and preclinical projects, R&D expenses amounted to €3.4m, 60% of which was dedicated to the IFNα KINOID programme and long-term follow-up of patients included in the Phase IIb study.

The Company pursued a diligent management policy in terms of administrative costs (€1.5m) and the number of employees remained stable over the period (25).

### FINANCIAL STRUCTURE

- The cash balance as at 30th June 2019 improved: €3.5m vs. €1.4m on 31st December 2018
- The Company's spending also decreased to an average of €0.7m per month during the first half of 2019 compared with €1.2m six months earlier.
- On the basis of an assessment of its financial needs, the available cash allows activities to be funded until the first quarter of 2020. However, in addition to its available cash, the Company maintains a funding capacity of approximately €6.5m (divided into TRANCHEs), subject to certain contractual conditions, through the "ORNANE" funding agreement, for a maximum amount of €10m implemented on 25 March 2019 (see section II below), to extend this visibility.

The 2019 half-yearly financial report will be made available to the public and filed with the AMF 30th October 2019. It will be made available on the company's website (www.neovacs.fr).

## 3) ORNANE FUNDING PROGRAMME SET UP ON 25 MARCH, 2019 AND ADDITIONAL TRANCHE (ORNANE 2) SET UP ON 23 MAY, 2019

Neovacs issued a third TRANCHE of 125 ORNANEs for a total nominal amount of €1,250,000 as part of the funding programme with the European Select Growth Opportunities Fund for a maximum nominal amount of €10 million (the "Investor")[2].

In accordance with the terms of the funding agreement, the issued ORNANEs were subscribed to at a price equal to 100% of their nominal value, which was paid up to an amount of €780,000 in cash, with the balance paid by offsetting against the Investor's receivable from the Company following the completion of the profit-sharing programme set up between the Investor and the Company in connection with the issuance of the second ORNANE[3] TRANCHE.

As a result of the completion of the profit-sharing programme set up between the Additional Investor and the Company in connection with the issuance of the additional TRANCHE (ORNANE 2)[4], Neovacs also issued 41 ORNANE 2 for a total nominal amount of €410,000, paid by offsetting the receivable.

The characteristics of the ORNANEs are detailed in the Company's press release dated 25th March 2019. ORNANE 2 have the same characteristics as an ORNANE.

The Company maintains on its website a monitoring table of the ORNANEs, ORNANE 2s and the number of Neovacs shares in circulation.

The ORNANEs resulting from the drawing of the third TRANCHE and the ORNANE 2s were issued on the basis of the 9th resolution of the ordinary and extraordinary general meeting on 29th May 2019, which granted the Board of Directors, with the option to subdelegate, a delegation of authority to decide on the issuance of shares and/or debt securities and/or transferable securities giving immediate or future access to the capital or giving the right to a debt security, to a benefit of a category of beneficiaries.

During its meetings of 27th September 2019 and 2nd October 2019, the Board of Directors made use of this delegation and issued the ORNANEs and ORNANE 2s, in accordance with the terms and conditions of the funding agreement.

It is specified that the aforementioned issues will not lead to a prospectus being prepared subject to AMF approval.

The tables below show the impact of the issuance and conversion of the third ORNANE TRANCHE and the newly issued ORNANE 2s:

[2] Company press release dated 25th March 2019.

[3] Company press release dated 23rd May 2019.

[4] Company press release dated 23rd May 2019.

| | Shareholder participation (in%) | |
|---|---|---|
| | Undiluted Basis | Diluted basis (after exercice of all dilutive instruments existing to date) |
| Before issuance | 1,00% | 0,88% |
| After issuance of the new Neovacs shares resulting from the conversion of the 3rd Tranche (including set-off against receivable) | 0,90% | 0,81% |
| After issuance of the new Neovacs shares resulting from the conversion of the additional tranche ORNANE 2 (set-off against receivable) | 0,88% | 0,79% |

| | Shareholders equity per share ratio (in €) | |
|---|---|---|
| | | |
| | Undiluted Basis | Diluted basis (after exercice of all dilutive instruments existing to date) |
| Before issuance | 0,033 € | 0,096 € |
| After issuance of the new Neovacs shares resulting from the conversion of the 3rd Tranche (including set-off against receivable) | 0,038 € | 0,078 € |
| After issuance of the new Neovacs shares resulting from the conversion of the additional tranche ORNANE 2 (set-off against receivable) | 0,039 € | 0,079 € |

## 4 ) CAPITAL REDUCTION

In accordance with the seventeenth resolution voted on and adopted by the shareholders at the general meeting of 29 May, 2019, the Company Board of Directors decided to proceed with a capital reduction as a result of losses, by reducing the nominal value of the Company's shares, from fifteen euro cents (€0.15) to five euro cents (€0.05).

The share capital was therefore reduced by €14,411,703.80 from €21,617,555.70, divided into 144,117,038 shares of €0.15 each to €7,205,851.90 divided into 144,117,038 shares of €0.05 each, the number of shares remaining unchanged.

The amount of the capital reduction was allocated to the "Negative Retained earnings" account to offset previous losses recorded in this account, thus reducing it from €108,318, 258 to €93.906.554. This operation has no impact on the number of shares in circulation and shareholders have no auction to take.

**About Neovacs**
Listed on Euronext Growth since 2010, Neovacs has become a major player in therapeutic vaccines targeting the treatment of autoimmune and inflammatory diseases and certain cancers. Thanks to its innovative technology inducing a polyclonal immune response, possibly protected until 2032 by four patent families, Neovacs is focusing its clinical development efforts on IFNα KINOID for the treatment of lupus. Neovacs also carries out preclinical work on other therapeutic vaccines for the treatment of allergies. The aim of this "KINOID approach" is to enable patients to better cope with a life-long treatment that would be more effective.
**For more information:** www.neovacs.fr

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