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## NEOVACS REPORTS FIRST-HALF 2015 FINANCIAL RESULTS

**Paris and Boston, October 2, 2015 – NEOVACS (Alternext Paris: ALNEV)**, a leader in active immunotherapies for the treatment of autoimmune diseases, today announced its results for the six months ended June 30, 2015, as approved by the Board of Directors on October 1, 2015.

### MAIN OPERATIONAL MILESTONES SINCE JANUARY 2015

- ◆ Initiation of Phase IIb clinical trial of IFN $\alpha$ -Kinoid to treat Systemic Lupus Erythematosus (« SLE ») or lupus, based on promising preclinical and clinical results to-date;
- ◆ Extension of IFN $\alpha$ -Kinoid development program to include dermatomyositis, an orphan condition where a positive IFN $\alpha$  signature plays a decisive role, following a recommendation by Neovacs' Scientific Advisory Board (SAB);
- ◆ Formation of a Neovacs U.S. subsidiary to strengthen the Company's presence in the country and expand clinical activity beyond the EU to the U.S. market;
- ◆ Significant strengthening of Company's cash position following a successful capital increase subscribed by U.S. institutional investors. Cash and cash equivalents totaled €12.3 million as of June 30, 2015.

*"In first half of 2015, we actively pursued the development of IFN $\alpha$ -Kinoid, our lead active immunotherapy product while maintaining tight control on expenses. The funds we raised during June in the U.S. have strengthened our cash position and given us the means to move forward on two key programs for IFN $\alpha$ -Kinoid: first in SLE with the launch of IFN-K-002, a Phase IIb clinical trial of IFN $\alpha$ -Kinoid ; secondly in dermatomyositis with a Phase I/IIa trial expected to commence in the first half of 2016."* commented Miguel Sieler, CEO of Neovacs.

## HALF-YEAR 2015 FINANCIAL HIGHLIGHTS

in K€	June 30, 2015	June 30, 2014
Revenues	94	57
Operating costs	5,714	4,576
<i>Of which R&amp;D</i>	4,724	3,594
Operating profit/loss	-5,620	-4,518
Net financial income/expense	-205	-64
Pretax profit/loss	-5,825	-4,582
Exceptional items	-48	49
Research Tax Credit	1,003	673
Net profit/loss	-4,870	-3,861

### Anticipated increase in R&D costs with the initiation of IFN-K-002 clinical trial in SLE

Operating costs were €5.7 million for the six months ended June 30, 2015, a 25% increase compared to the period ended June 30, 2014. This increase was primarily the result of the initiation of the Phase IIb clinical trial of IFN $\alpha$ -Kinoid in SLE. R&D expenses were 82% of the Company's total operating costs for the first half of 2015, totaling €4.7 million compared to €3.6 million in the same period last year. General and administrative expenditures remained under tight control while Neovacs increased focus on its emerging R&D effort.

Consequently, half-year operating losses increased 24% to €5.6 million, in line with Company expectations. This compares to €4.5 million in operating losses in the first half of 2014.

After taking into account €1 million in Research Tax Credit, the net loss for the six months ended June, 30 2015 was €4.8 million compared to €3.9 million for the same period in 2014.

### Significant strengthening of financial resources

Neovacs raised €7.5 million in June 2015 through a capital increase subscribed by three U.S. institutional investors. The funds raised significantly improved the Company's cash position and strengthened its financial visibility.

To address its long term financing needs, Neovacs secured a flexible, multiyear equity financing with Kepler Cheuvreux in November 2014. As stated previously, this equity line, through which Neovacs can access up to €20 million is arranged in three tranches of optional equity financing, one of €7 million and two of €6.5 million each. However, Neovacs has committed not to use this equity financing until after December 31, 2015.

As a result, available cash balances as of June 30, 2015 were €12.3 million, compared to €2.9 million as of June 30, 2015. Neovacs believes it has the financial resources to cover its expenditures until September 2016. To increase its cash runway, the Company reserves the possibility to utilize the 3<sup>rd</sup> tranche of optional equity financing set up with Kepler Cheuvreux.

## HALF-YEAR 2015 CLINICAL AND OPERATIONAL HIGHLIGHTS

- **New members joined Neovacs' Scientific Advisory Board (SAB) to support the shift in therapeutic focus**, with a greater emphasis on pathologies targeted by IFN $\alpha$ -Kinoid and VEGF $\alpha$ -Kinoid. Professor Banchereau, Ph.D., remained SAB chairman. The SAB guides Neovacs' clinical development strategy.
- **Preparation of IFN-K-002, a Phase IIb trial to assess the biological efficacy and clinical response of IFN $\alpha$ -Kinoid in moderate to severe forms of SLE** in 19 countries in Europe, Asia and Latin America. The Company plans to file an IND for a trial in SLE with IFN $\alpha$ -Kinoid (Phase IIa) in the U.S. in early 2016.
- **Expansion IFN $\alpha$ -Kinoid's clinical program to dermatomyositis**, an orphan indication in which a positive IFN $\alpha$  signature plays a decisive role. Neovacs plans to conduct a multi-center Phase I/IIa trial of IFN $\alpha$ -Kinoid in adult dermatomyositis in 30 patients in 2016.
- **Strengthening of U.S. presence** with the formation of a wholly-owned U.S. subsidiary, Neovacs, Inc., headquartered in Boston. The role of Neovacs, Inc. will be to raise the profile of the Company within the medical and financial communities in the U.S.. Neovacs, Inc. will work directly with the U.S. Food and Drug Administration as the Company prepares to initiate clinical trials in the U.S.
- **Collaboration agreement with Stellar Biotechnologies**. The two companies entered into an expanded supply agreement to meet Neovacs' requirements for Keyhole Limpet Hemocyanin (KLH), a primary component of Neovacs' proprietary Kinoid immunotherapy technology, for its planned clinical trials and for expected commercial manufacturing of IFN $\alpha$ -Kinoid.

## SUBSEQUENT EVENTS AND OUTLOOK

- **Initiation of Phase IIb clinical trial in SLE**. Neovacs has begun enrolling patients in IFN-K-002, a Phase IIb clinical trial to evaluate the efficacy of IFN $\alpha$ -Kinoid in SLE, after being granted first approvals by regulatory agencies and ethics committees in several European countries. The first centers of the trial are now active. Results of the clinical trial are expected in the first quarter of 2017.
- **Presentation of extended follow-up data of IFN $\alpha$ -Kinoid in SLE** during *Lupus 2015*, the 11<sup>th</sup> International Congress on Systemic Lupus Erythematosus (SLE), which took place from September 2-6, 2015 in Vienna, Austria<sup>1</sup>. Collected as part of the extended follow-up study of the Phase I/IIa trial of IFN $\alpha$ -Kinoid in lupus, this new data demonstrates that IFN $\alpha$ -Kinoid induces a lasting, polyclonal, neutralizing anti-IFN $\alpha$  response in SLE patients.

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<sup>1</sup> J. Ducreux, et al, Lupus 2015, Poster Session P04 Treatment.

**About Neovacs**

Created in 1993, 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 five patent families that potentially run until 2032) Neovacs is focusing its clinical development efforts on IFN $\alpha$ -Kinoid, an immunotherapy being developed for the indications of lupus and dermatomyositis. 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.

**For more information on Neovacs, please visit [www.neovacs.fr](http://www.neovacs.fr)**

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