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Neovacs SA: Pioneering an Innovative Approach to Modern Immunotherapy; Making Progress in Multiple Fronts

Company Update:

Since our initiation of coverage on February 6, 2017, Neovacs SA ("Neovacs") has made achievements in various areas such as being granted a patent in China, entering into the third commercial licensing agreement, completion of patient enrollment for a phase IIb clinical study, and its Investigational New Drug (IND) application for dermatomyositis has been approved by the U.S. Food and Drug Administration (FDA).

Key Points

- On 9 February 2017, Neovacs, a French biotechnology company listed on the Alternext Paris market (Bloomberg ticker symbol: ALNEV FP), announced that it had been **granted by the Chinese Patent Office (SIPO) a new patent** – "Method of treatment of a disease related to the overexpression of IFNα". Neovacs has also filed this patent in all major markets worldwide to cover the use of its IFNα Kinoid vaccine for all diseases characterized by an overexpression of the cytokine, Interferon alpha (IFNα), including Systemic Lupus Erythematosus (SLE) or lupus, dermatomyositis (DM) and type-1 diabetes. This patent provides protection until 2032, with a possibility of further extension.

- Following the signing of a commercial licensing agreement for the South Korean market in 2016, Neovacs made public on 21 February 2017 the **entering into a commercial license option agreement with BioSense Global LLC**, a biotechnology company, for its IFNα Kinoid vaccine to treat lupus and DM in China. The license agreement is **worth up to EUR65 million** in upfront and milestone payments, and Neovacs is also eligible for double-digit sales royalties.

Price (24 Jul'17): EUR0.79

Market Data (24 Jul'17):

52-Wk High: EUR1.12 (21 Feb'17)
52-Wk Low: EUR0.67 (31 Oct'16)
52-Wk Range: EUR0.45
Market Cap: EUR41.4M
Shares Outstanding: 52.4M
Shares Floating: ~44.2M-48.2M

- Neovacs reported 2016 annual results on 30 March 2017. Due to advances in the clinical development of the company's vaccine programs, operational expenditure for the year was approximately EUR17.6 million, up 41.7% YoY. As of 31 December 2016, Neovacs had EUR3.9 million in cash and cash equivalents. The company plans to forge more partnerships in 2017 in an effort to further control its costs longer term while maintaining ownership of its technology.

- Neovacs exercised its option to access the Tranche 2 equity financing line established with Kepler Cheuvreux to strengthen its capital base. In relation to that, Neovacs issued 4.66 million new common shares to Kepler and received EUR3.7 million in cash, equivalent to an issuance price of EUR0.79 per share.

- Neovacs announced on 20 June 2017 the **completion of the worldwide, randomized and multi-center patient enrollment (N=178)** for its phase IIb clinical study for IFN-K-002, **evaluating IFNα Kinoid for the treatment of lupus**, evidencing the interest of clinicians in the company's novel therapeutic approach. As a result, **operational expenditure is expected to come down in 2017**.

- On 5 July 2017, Neovacs announced its third licensing agreement for its IFNα Kinoid technology. This is an exclusive license agreement signed with **Centurion Pharma** for the treatment of lupus in the territory of **Turkey**. Pursuant to the terms of this agreement, Neovacs will receive **a total of EUR6 million**, including an upfront payment at signature and additional potential payments based on achievements of predefined clinical and regulatory milestones. Neovacs is also subject to receiving double-digit royalties on net sales of the vaccine in Turkey. Centurion Pharma will begin negotiations with local health authorities in Turkey to obtain an agreement to market IFNα Kinoid in lupus on a "Named Patients" program basis, meaning that doctors can prescribe the vaccine because patients have a special need for it.

- The ongoing Phase IIb clinical trial of IFNα Kinoid in lupus has received the third positive data review by the Independent Data and Safety Monitoring Board (IDSMB), which **found no safety concerns** and recommended the continuation of the study without any adjustment.

- Neovacs announced on 19 July 2017 that the **U.S. FDA has cleared its Investigational New Drug (IND) application** for IFNα Kinoid for the dermatomyositis indication, allowing Neovacs to extend its Phase IIa clinical trial (already on-going in Europe) to the U.S., where investigators have showed interest in the technology.

Industry Update:

Seeking to significantly streamline its drug review process, China Food and Drug Administration (CFDA) has proposed a new set of rules to hasten the clinical trial application process and **speed up foreign drug approvals in China** by simplifying the registration procedures.

- The CFDA is beginning to align with the U.S. Food and Drug Administration's (FDA) Investigational New Drug (IND) trial approach, implementing a "no response means approval" mechanism. This would drastically cut down the waiting time for drug researchers and developers before starting their clinical trials in China by eliminating the dependence upon China's current resource-strapped approval process.
- Under the current system, a drug company must wait for CFDA's approval before commencing a clinical trial. According to L.E.K Consulting, a life sciences consulting firm with CFDA experience, it takes an estimated 195 days on average for a response from the CFDA. CFDA officials acknowledge the approval process is a bottleneck in the drug development process. In accordance with the new system, a company is given 60 working days (in contrast to 30 days under the U.S. FDA procedures) for the CFDA to either question or reject a trial application, and a "no response" from the CFDA within 60 days means the company can proceed with the clinical study. This approach significantly relieves CFDA's burden, stemming from the voluminous applications pending approval.
- Foreign drug registration rules will be revised by the CFDA, effectively accelerating the approval of foreign developed drugs. These proposed changes aim at integrating China into global drug developments.
    - Currently, foreign drug makers must have a drug at least begun a phase II trial at a non-Chinese testing site before the CFDA would approve a bridging study to start in China. Under the proposed rules, foreign companies will be allowed to begin clinical trials in China regardless of the clinical progress of their drugs.
    - More importantly, these revised policies will also allow foreign drug makers to file a new drug for approval using clinical trial data from international, multicenter trials, as long as China is

included as a study site. At present, a China-specific trial is required for most new foreign drug approval filings, which in some cases, require a drug maker to start all over, launching phase I clinical trials in China even though the drug may have entered or even completed phase II trials elsewhere.

- The CFDA is exploring the option to grant conditional approvals for treatments targeting orphan indications that typically include conditions for which there are significant unmet medical needs, and allow a drug's approval to be supported by early or mid-stage data with proven clinical benefits. Although a drug may be marketed at an earlier phase, follow-up studies are required to complete the full cycle of clinical research.
    - This would closely resemble European Medicines Agency's (EMA) "conditional marketing authorization" and the U.S. FDA's "breakthrough therapy" or "fast-track" programs. Although China has previously granted such approvals for various foreign drugs satisfying CFDA's conditions, it is the first time this approach is officially included as part of the authority's policy.
    - Several pre-requisites have to be addressed prior to the implementation of this particular policy. First, the CFDA will have to set a benchmark for a disease (mainly by the prevalence rate) to be classified as an orphan disease in China. Moreover, the CFDA and the Chinese government need to institute a legal framework to support the pursuit of development of certain drugs. This includes defining parameters such as the number of years of market exclusivity (orphan drug exclusivity is 7 years for U.S. FDA and 10 years for EU EMA), medical expense reimbursement, and R&D tax credit.

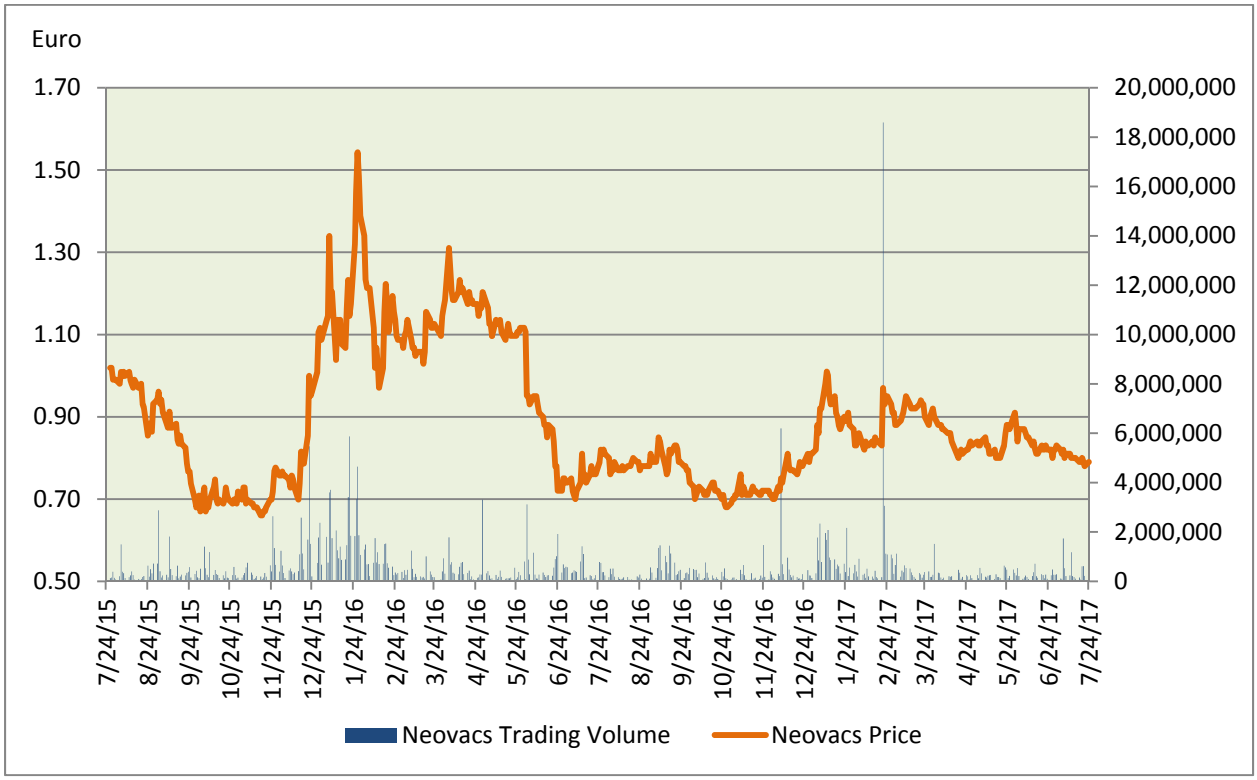
Implications of CFDA's Proposed Changes:

- These changes will provide Neovacs and other foreign drug developers with significant advantages, as the proposed CFDA regulations will offer not only more visibility but also **eliminate redundant clinical trial costs** with respect to achieving approval for marketing in the Chinese market.
- More importantly, the indications (lupus and dermatomyositis) that Neovacs' therapeutic vaccines are targeting **could potentially meet the CFDA's criteria to be classified as orphan diseases** such that **marketing can occur concomitantly with clinical trials**, similar to the strategy the company is pursuing in South Korea. Classifying these indications as orphan diseases could substantially accelerate Neovacs' timeline to marketing and subsequently improve the company's organic cash inflows. In addition, Neovacs' distribution network in China is expected to benefit from its commercial license partner, BioSense, which has the expertise in developing, registering and commercializing products.

Upcoming News Flow:

- Preliminary results of the Phase IIa clinical study for dermatomyositis are anticipated in the **second half of 2017**. Neovacs expects the data to confirm the biological activity of their IFNα vaccine, enabling the company to file an "orphan drug designation" application.
- Availability of the Phase IIb IFN-K-002 study results for IFNα Kinoid in lupus is expected in **2Q 2018**.
- Positive results from the preclinical proof of concept by using IFNα Kinoid in type-1 diabetes could warrant the launch of a Phase II clinical development during the **first half of 2018**.

Exhibit 1: 2-Year Share Price Performance and Trading Volume for Neovacs



Source: Bloomberg, Cedrus Research

IMPORTANT DISCLOSURES

STOCK OWNERSHIP AND CONFLICT OF INTEREST DISCLOSURE

- Neither Randy Hice nor any member of the research team or their households is an owner of Neovacs SA common shares.

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Randy Hice hereby certifies that the views expressed in this research report accurately reflect his personal views about the subject companies and their securities. He also certifies that he has not been, and will not be, receiving direct or indirect compensation in exchange for expressing the specific recommendations in this report.

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