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Neovacs Announces FDA Acceptance of a New IND to Expand in U.S. IFNα Kinoid Clinical Development Program in Dermatomyositis

This is the second clinical trial approved by the FDA for Neovacs' lead product candidate

Paris and Boston, July 19th, 2017 – 7:30 am CET - Neovacs (Euronext Growth Paris: ALNEV) a leader in active immunotherapies for the treatment of autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for IFNα Kinoid in the treatment of dermatomyositis, which allows the Company to initiate in the US its Phase IIa clinical trial already on-going in European countries.

Miguel Sieler, CEO of Neovacs, commented: "*FDA clearance of a new IND application is an important milestone for the development of our IFNα Kinoid technology. The data obtained in lupus with IFNα Kinoid have been positively evaluated by FDA, which supports the application of our vaccine in dermatomyositis. Therefore, we are focused on advancing IFNα Kinoid through the clinic, as expeditiously as possible, in the context of an orphan disease with a high unmet medical need. We are excited about expanding this clinical trial to the United States, where many renowned investigators have expressed their interest in our technology.*"

This Phase IIa clinical trial is a multicenter study currently being conducted in Europe (France, Italy, Germany, and Switzerland) in 30 adult patients. The objective of the study is to evaluate the immunogenicity, tolerability, and biological and clinical efficacy of IFNα Kinoid in this new indication. The results of this study are expected to support the design and execution of a pivotal study.

About Dermatomyositis

Dermatomyositis (DM) is a rare, autoimmune and inflammatory disease characterized by severe skin lesions and muscle weakness with varying impact on physical abilities. Other systems may also be impacted (vascular, pulmonary, gastrointestinal and cardiac). The DM affects mostly children. It is twice more common in women than in men. In adults, one in three patients with DM may develop cancer within three years of the first manifestations of the disease. The prevalence is estimated between 1/50,000 and 1/10,000[1], which confers the status of orphan disease in Europe and United States

DM is a disease driven by the overproduction of the cytokine Interferon alpha (IFNα) [2]. Corticosteroids are used as first line therapy, immunosuppressants could be added in refractory cases or as corticosteroid-sparing agents. No biological therapy is currently approved in DM.

[1] *http://www.orpha.net/consor/cgi-bin/OC_Exp.php?Expert=221&lng=FR*

[2] Walsh 2007, Bilgic 2009, Higgs 2011, Greenberg 2012 & Allenbach 2016, Salajegheh 2010, Suarez-Calvet 2014, Walsh 2007

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 five 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 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

Contacts

Contacts
NEOVACS – Corporate Communication & Investor Relations
Charlène Masson
+33 (0)1 53 10 93 14
cmasson@neovacs.com

NEWCAP- Press relations
Annie-Florence Loyer
+33 1 44 71 00 12 / + 33 6 88 20 35 59
afloyer@newcap.fr

Léa Jacquin
+33 1 44 71 20 41 / +33 6 58 14 84 66
ljacquin@newcap.fr

LIFESCI ADVISORS- Investor Relations / Financial Communications
Chris Maggos
+41 79 367 6254
chris@lifesciadvisors.com