ABIVAX completes recruitment in its phase IIb/III pivotal study with ABX203, first-in-class therapeutic vaccine against Chronic Hepatitis B

Paris, 24th September 2015 – ABIVAX (Euronext Paris: FR0012333284 – ABVX), a leading clinical stage biotech company developing and commercializing therapeutic anti-viral drugs and vaccines, today announced that it has completed enrollment of all 266 subjects into its pivotal Phase IIb/III clinical trial of ABX203, aimed at demonstrating the safety and efficacy of ABX203, a therapeutic vaccine candidate for the treatment of patients with chronic hepatitis B disease. This is a significant milestone for the company, which recently conducted an IPO on the regulated market of Euronext Paris and set a record among biotechnology companies in France in terms of the amount of funds raised.

"*We are delighted to announce that ABIVAX has successfully and rapidly fully enrolled 266 patients for this essential study. The enthusiasm of the physicians and investigators involved in the study is evident. This not only highlights the interest in our innovative therapeutic vaccine, but also underlines the medical need for immunotherapy in this indication. This is an important milestone for ABIVAX that should enable us to generate the first study results in Q4/2016,*" said Prof. Hartmut J. Ehrlich, M.D., CEO of ABIVAX.

"*We are very pleased with this important clinical development milestone that demonstrates the efficiency of the relationship between ABIVAX and the CIGB,*" added Luis Herrera Martinez, CEO of the Cuban Center for Genetic Engineering and Biotechnology (CIGB), and Gerardo Guillén Nieto, Director of Biomedical Investigation at the CIGB.

Chronic Hepatitis B (CHB) virus infection is a very severe disease that often leads to life-threatening complications such as cirrhosis and liver cancer. There are approximately 350 million chronic carriers of Hepatitis B virus (HBV) worldwide, and between 1.0 and 1.5 million people die each year from these complications. CHB is present worldwide but its prevalence is highest in Sub-Saharan Africa and in East Asia.

The ABX203 phase IIb/III study is an open-label, randomized, comparative study designed to assess the efficacy of ABX203 to maintain control of Hepatitis B disease after cessation of nucleotide analogs, in particular in controlling viral load for a much longer period of time when compared to current treatment options. This study is ongoing in seven Asian/Pacific countries (Taiwan, Hong-Kong, Thailand, Singapore, South Korea, Australia and New-Zealand). In this large scale controlled and randomized study, one group of patients will receive ABX203 for 24 weeks, in addition to the current standard of care (nucleoside analogues, NUCs, along with alpha interferon); therapy will be stopped after 24 weeks. These patients will be evaluated against a control group receiving NUCs only. The study's primary efficacy endpoint is the percentage of subjects with viral load <40 IU/mL at week 48, i.e 24 weeks after the treatment with ABX203 has been completed. Study results are expected in the fourth quarter of 2016.

ABX203 is a therapeutic vaccine composed of 2 recombinant proteins from HBV, the surface antigen (HBsAg) and the nucleocapsid (core) structure (HBcAg). It has been designed to induce the production of neutralizing serum antibodies to HBsAg and the induction of strong cellular responses, which are usually weak or undetectable in patients with CHB. These immune responses are similar to those that occur in patients with a self-resolving acute HBV infection. ABX203 is formulated as a nasal spray solution and as a solution for sub-cutaneous injection.

ABIVAX owns the development and distribution rights for ABX203 for more than 80 territories in Asia, Europe and Africa. These rights were licensed in 2013 from the Center for Genetic Engineering and Biotechnology (CIGB, Havana, Cuba) following the completion of successful phase I, I/II and III clinical trials run by the CIGB. These studies showed that ABX203 was well tolerated and had an antiviral effect similar to that of PEG-IFNα but that this effect on HBV viral load was, in contrast with PEG-IFNα, sustained for at least 6 months after treatment cessation. This unique sustained effect, in addition to a shorter duration of administration, means that ABX203 may offer important therapeutic advantages over standard treatments for CHB.

About ABIVAX

ABIVAX is an advanced clinical development biotech company focused on becoming a global leader in the discovery, development and commercialization of anti-viral drugs and human therapies to treat some of the world's most life-threatening infectious diseases, including HIV/AIDS and chronic Hepatitis B.

ABIVAX has 2 compounds in clinical stage research: ABX464 a novel small molecule against HIV with a number of important potential competitive advantages, and ABX203, a therapeutic vaccine candidate that could be a cure for chronic Hepatitis B. The broader ABIVAX portfolio includes additional anti-viral compounds and vaccines that may enter the clinical stage in the coming 18 months.

ABX464 has been developed using ABIVAX' anti-viral platform that allows the Company to address a broad range of viral targets involved in the production and management of viral RNA within the host cell. ABIVAX also has access to a number of cutting edge technologies including complex molecular protein/RNA-pro interactions to discover and develop proprietary breakthrough therapies to help patients' clear important pathogenic viruses.

Headquartered in Paris, France, ABIVAX conducts its research and development in Évry (France) and Montpellier (France). In addition, ABIVAX benefits from long term partnerships with the Cuban Center for Genetic Engineering and Biotechnology (Havana, Cuba), The Finlay Institute (Havana, Cuba), the Molecular Genetics Institute of Montpellier (CNRS-Université de Montpellier, France), the Curie Institute (Paris, France), the Scripps Research Institute (La Jolla, CA, USA), the University of Chicago (Chicago, IL, USA), Brigham Young University (Provo, UT, USA), and the Institut Pasteur (Paris, France). ABIVAX intends to pursue further business development opportunities to access commercial products as part of its overall corporate strategy.

ABIVAX was founded by Dr. Philippe Pouletty, M.D., managing partner at Truffle Capital, the cornerstone investor in ABIVAX since its creation. The company is listed on the regulated market of Euronext Paris, compartment B (ISIN code: FR0012333284 – Ticker: ABVX). For more information, please visit www.abivax.com.

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