ABX203 (HeberNasvac) Granted Cuban Marketing Authorization to Treat Chronic Hepatitis B

Paris, France December 8th 2015 – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing anti-viral and vaccine therapies for diseases like HIV/AIDS and chronic Hepatitis B (CHB) and the Center for genetic Engineering and Biotechnology (CIGB), a global leader in biotechnology, today announced that CECMED, the Cuban regulatory authorities, granted the CIGB their first marketing authorization application for ABX203, a first-in-class therapeutic vaccine for treatment of CHB, under the trade name HeberNasvac.

"The immune responses observed in CHB patients receiving ABX203, during clinical testing, clearly show that the therapeutic vaccine is able to help patients overcome the immune paralysis which is so typical for the chronic form of the disease," said Gerardo Guillen, PhD, Director of Biomedical Research at the CIGB in Havana. *"The previous studies with ABX203 provided clinical proof of the concept of therapeutic vaccination in chronic Hepatitis B. ABX203 (HerberNasvac) has demonstrated a unique sustained effect, which was achieved with a shorter duration of administration and better tolerability than peg-interferon (PEG - IFNα). In other words, the data indicate that ABX203 could deliver considerable therapeutic advantages over standard treatments for patients suffering from CHB."*

ABX203 is formulated as a nasal spray solution and as a solution for sub-cutaneous injection and has been designed to induce neutralizing serum antibodies to HBsAg as well as strong cellular responses, which are weak or undetectable in patients with CHB. The therapeutic vaccine is composed of 2 recombinant proteins from the Hepatitis B virus (HBV), the surface antigen (HBsAg) and the nucleocapsid (core) antigen (HBcAg).

ABIVAX owns development and commercial rights for ABX203 for more than 80 countries in Asia, Europe and Africa. These rights were licensed in 2013 from the CIGB following the completion of successful phase I, I/II and III clinical trials run in Cuba and Bangladesh. These studies showed that ABX203 was well tolerated and had an antiviral effect similar to that of PEG- IFNα. In addition, the effect on HBV viral load was sustained for a longer period of time. This unique prolonged efficacy, after shorter, more convenient administration, suggests that ABX203 offers considerable therapeutic advantages and improved compliance over standard treatments for CHB.

Professor Hartmut Ehrlich, M.D., CEO of ABIVAX commented: *"We are very pleased with this first Marketing Authorization Approval (MAA) approval for ABX203. It represents a significant milestone for the CIGB, ABIVAX and, most importantly, patients suffering from chronic Hepatitis B. We are looking forward to making this long lasting treatment available to the millions of patients who currently need daily, life-long treatment to control this devastating disease."*

The CIGB has a track record of successful market introductions, reflecting the quality and standard of their products. For example, their prophylactic vaccine for Hepatitis B is registered in more than 50 countries, and more than 200 million doses have been administered, leading to an international reputation for excellence.

Furthermore, this first MAA in Cuba will allow rapid filing of the data used by the Cuban regulatory authorities, for marketing authorization applications in some key ABIVAX countries.

Additionally, ABIVAX is currently conducting its own late-stage «pivotal» phase IIb/III clinical trial with ABX203. This controlled, randomized, blinded study is already fully recruited (276 patients) and is being conducted at over 40 clinical centers in seven Asia-Pacific countries (Australia, New-Zealand, Taiwan, Hong-Kong, Thailand, Singapore, and South Korea). The results are expected to be reported in the fourth quarter of 2016.

In this ongoing pivotal study, one group of patients is receiving for 24 weeks ABX203 plus the current standard of care (nucleotide analogues, NUCs) and the control group is receiving NUCs only. All therapy is stopped after 24 weeks of combination treatment. The study's primary efficacy endpoint is the percentage of subjects with viral load <40 IU/mL 24 weeks after the treatment with ABX203 has been completed. Study results are expected, if positive, to support further approvals of ABX203, particularly in the Asia-Pacific region, where the majority of the patients with CHB reside.

About Chronic Hepatitis

Hepatitis B virus (HBV) infection is a major public health problem which has an important deleterious socioeconomic impact worldwide. Chronic HBV infection (CHB) causes or contributes to development of a broad spectrum of liver disease and early mortality.

According to the World Health Organization (WHO), an estimated 2 billion people worldwide have been infected with HBV, and more than 350 million people, or 5% of the world's population, suffer from lifelong CHB infections. CHB infection is an established cause of cirrhosis, liver failure and liver cancer. It is the cause of up to 80% of hepatocellular carcinomas (HCC). Around 1 to 1.5 million people die every year due to the consequences of hepatitis B.

With nearly 200 million people worldwide with CHB, South-East Asia and the Pacific Regions account for ¼ of the world population and bears 30% of world's total disease burden. In Europe there are estimated to be 14 million people suffering from CHB.

ABIVAX is an emerging global leader in the discovery, development and commercialization of anti-viral therapeutics and vaccines 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 first-in-class resistance-proof oral small molecule HIV/AIDS therapy; and, ABX203, a therapeutic vaccine that could cure chronic Hepatitis B. ABIVAX also is advancing additional anti-viral compounds and therapeutic vaccines that may enter the clinical stage in the coming 18 months. A recently updated corporate presentation, which includes a timeline for the company's anticipated news flow, is available at www.abivax.com .

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