



ABIVAX Recruits First Patient in a Pivotal Phase IIb/III clinical trial with ABX203, a novel immunotherapy against chronic hepatitis B

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Details

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Paris, February 26, 2015 – ABIVAX, a clinical stage biotech company developing and commercialising anti-viral compounds and human vaccines, today announced that it has dosed in New Zealand the first patient in a Phase IIb/III clinical trial of ABX203 which is taking place in several countries of the Asia-Pacific region. The study is designed to assess whether ABX203 can deliver a significant improvement in the treatment of chronic hepatitis B (CHB) via controlling viral load for a much longer period of time when compared to current treatment options.

ABX203 is a therapeutic vaccine composed of 2 recombinant proteins from HBV, the surface antigen (HBsAg) and the nucleocapsid (core) structure (HBcAg). ABX203 has been designed to induce the production of neutralizing serum antibodies to HBsAg and the induction of strong cellular responses which are 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 distribution rights for ABX203 for more than 80 territories in Asia, Europe and Africa. They 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 CIGB in Cuba and Bangladesh. These studies showed that ABX203 was well tolerated and had an antiviral effect similar to that of PEG-IFN α but that this effect on HBV viral load was, in contrast with PEG-IFN α , 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.

Professor Christian Trepo, MD, one of the top hepatitis experts worldwide, commented: "The previous studies of ABX203 have provided clinical proof of the concept of therapeutic vaccination in chronic hepatitis B. Its unique sustained effect, in addition to a shorter duration of administration, means that ABX203 could deliver important therapeutic advantages over standard treatments for patients suffering from chronic hepatitis B."

The pivotal Phase IIb-III study is expected to be conducted at 50 clinical centres in 7 countries in the Asia-Pacific region. The study aims to recruit approximately 230 patients with HBeAg negative active chronic hepatitis B.

In this large scale study a group of patients will receive ABX203 for 24 weeks on top of their NUCs therapy (current standard of care together with PEG-IFN α) and these patients will be evaluated against a control group receiving only NUCs. The study will assess the following objectives at week 48 – 24 weeks after treatment with ABX203 has completed:

- Characterization of the level of sustained control of Hepatitis B disease following cessation of treatment with NUCs
- Assessment of safety and reactogenicity of ABX203
- Characterization of the antibody and cellular immune responses to ABX203

The results from this Phase IIb-III study are expected in Q3 2016. A positive outcome from this study is expected to allow ABIVAX to file for marketing approval in certain Asian countries.

Professor Hartmut Ehrlich, M.D., CEO of ABIVAX, said: "We are confident that ABX203, our therapeutic vaccine against chronic hepatitis B could be a major progress in the treatment of patients with this devastating disease. This pivotal Phase IIb-III study that we have announced today is designed to confirm that ABX203 can deliver meaningful clinical benefits in terms of long-term viral control, a goal that cannot be achieved today with the current standard of care."

Gerardo Guillen, PhD, head of R&D at CIGB in Havana commented: "This first-in class therapeutic vaccine is awaiting market approval in Cuba and we are very pleased to see the great progress our partner Abivax is making with the international development of this world leading immunotherapeutic to treat chronic hepatitis B".

About Chronic Hepatitis

Hepatitis B virus (HBV) infection is a major public health problem worldwide. Infection with HBV causes a broad spectrum of liver disease, including subclinical infection, acute self-limited hepatitis, and fulminant hepatitis. Persons infected with HBV can also develop persistent infection, which can lead to chronic disease and death from cirrhosis or hepatocellular carcinoma (HCC).

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

With nearly 200 million people with chronic HBV, South-East Asia and the Pacific Regions account for ¼ of the world population and bears 30% of world's total disease burden.

About ABIVAX

ABIVAX is an advanced clinical stage biotech company focused on becoming a global leader in the discovery, development and commercialization of anti-viral compounds and human vaccines to treat some of the world's most important 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.

For more information, please visit the company's website: www.ABIVAX.com

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