Abivax completes recruitment of ABX464 Phase IIa HIV study

Preliminary data report in January

Paris, France December 21st 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) today announced the completion of patient enrollment in its ongoing Phase IIa clinical study (ABX464-003).

"ABX464 is a first-in-class antiviral drug candidate for the treatment of patients with HIV-infection. It is an orally available small molecule inhibiting HIV replication through an entirely novel mechanism, which may confer significant advantages over competing drugs" said Prof Hartmut Ehrlich, M.D., Chief Executive Officer of Abivax. "For the first time in the treatment of HIV infection, this molecule could deliver a long lasting reduction of the viral load and potentially become the key to achieving a functional cure."

The ABX464-003 clinical study is an ongoing randomized, double-blind, placebo-controlled Phase IIa monotherapy dose-ranging study in HIV infected patients in Mauritius and in Thailand who have never received antiviral drugs. The patients in the 25, 50, 75, 100 and 150 mg dose cohorts, were administered the drug-candidate orally once daily for only 3 weeks. Each dose cohort consists of 6 patients treated with ABX464 and 2 patients receiving placebo.

"The completion of the enrollment in the 150 mg dose cohort this week enables ABIVAX to confirm that the preliminary analyses of data from this three-week study will become available in January 2016," said Jean-Marc Steens, M.D., Chief Medical Officer of Abivax. "Data from this study will be key to selecting the appropriate doses for future studies designed to study the long-lasting efficacy of ABX464."

The primary endpoint of this study is to evaluate the safety and tolerability of ABX464 after repeated oral administrations of five different doses. Secondary endpoints will examine its pharmacokinetic profile and its impact as a monotherapy on the viral load.

AIDS was first identified in the United States in 1981 and HIV was first discovered in France in 1983. Since then the disease has spread and continues to constitute a global health issue that, according to the World Health Organization (UNAIDS fact sheet December 2015), has claimed more than 25 million lives worldwide. In 2014, UNAIDS estimated at 36.9 million the number of people still living with the virus, with an additional 2 million becoming newly infected each year.

Treated with anti-retroviral therapy, HIV/AIDS has become a chronic infection but remains a deadly disease that places a significant burden on healthcare resources. ABIVAX estimates the total worldwide cost for anti-HIV drugs to be around $18 billion annually.

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 recently approved in Cuba and in late-stage clinical development in other countries 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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