ABIVAX announces positive top---line clinical Phase IIa data for novel HIV drug---candidate ABX464

ABX464 was safe and demonstrated dose---dependent antiviral activity in HIV---infected, treatment---naïve patients

Paris, France January 11th 2016 – 6pm – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing novel antiviral therapies for diseases like HIV/AIDS and chronic Hepatitis B (CHB), today announced positive top---line efficacy and safety results from the Company's Phase IIa clinical study (ABX464---003) in patients with HIV infection.

"These exciting preliminary data reinforce our confidence in the potential of ABX464 to become a key component of a functional cure for HIV/AIDS thanks to its unique and novel mechanism of action," said Prof. Hartmut Ehrlich, M.D., Chief Executive Officer of ABIVAX.

ABX464 is a first---in---class orally available antiviral drug candidate for the treatment of patients with HIV infection. It blocks HIV replication through a unique mechanism of action that leads to the destruction of viral RNA. Previously reported preclinical data in humanized mice demonstrated that ABX464 monotherapy had an antiviral effect which was sustained for at least 6 weeks following treatment interruption (Campos et al, Retrovirology 2015, 12:30).

The ABX464---003 clinical study was a randomized, double---blind, placebo---controlled Phase IIa monotherapy dose---ranging study in HIV infected patients who have not previously received antiviral drugs. Patient cohorts were administered ABX464 in increasing doses once daily for up to 3 weeks. Each dose cohort consisted of 6 patients treated with ABX464 and 2 patients receiving placebo.

A dose---dependent increase in the response rate to ABX464 monotherapy was observed in the study. The majority of patients who received the highest dose (150 mg) showed a viral load reduction of at least 0.5 log (greater than 68% reduction) during the treatment period. No such change was observed in any of the corresponding placebo patients.

The safety data from this study indicate that ABX464 was welltolerated. There were no severe and/or serious adverse events that were ABX464---related. The observed adverse events (mainly headache, nausea and emesis) were predominantly mild and sometimes moderate in nature.

*"Having been associated with the development of ABX464 from the beginning, I am pleased to see the preclinical efficacy profile of this novel drug candidate now translating into clinical data, with anti---viral responses observed at the higher doses in this early stage and relatively short monotherapy study,"*said Prof. Mark Wainberg, Ph.D., Head of the McGill University AIDS Centre in Montreal, Canada and member of ABIVAX' Scientific Advisory Board. *"Patients globally are in critical need of new and innovative therapies for HIV disease, and ABX464 has the potential to fillan important treatment gap."*

ABIVAX will present more detailed results from this study at several scientific conferences in the coming months.

The primary goal of ABX464 clinical development is to optimize an ABX464---based treatment regimen that could result in a long---lasting functional cure upon treatment cessation in patients who respond to ABX464.

Prof. Jacques Reynes, M.D., Head of the Infectious Diseases Department at Montpellier University Hospital and Principal Investigator of the next study with ABX464 commented,"*The results of this first study in HIV---infected patients encourage us to start the next Phase IIa study in which different doses and combination with other HIV therapies will be explored. Research on biomarkers predicting ABX464 efficacy will be part of the next and forthcoming studies*".

AIDS was first identified in the United States around 1981, and the HIV virus was 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 eachyear.

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 bilion annually.

ABIVAX is an emerging global leader in the discovery, development and commercialization of anti---viral therapeutics and therapeutic 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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