ABIVAX to celebrate World AIDS Day with an update on the development of its HIV therapeutic candidate, ABX464

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Paris, France, November 24th 2015 – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing anti-viral drugs and therapeutic vaccines for diseases like HIV/AIDS and chronic hepatitis B (CHB), today announced that it will participate in World AIDS Day, on December 1st, by celebrating the progress it has made in developing a potentially breakthrough treatment for HIV/AIDS, ABX464.

ABX464 is a first-in-class, orally available small molecule drug candidate, which is in mid-stage clinical evaluation in HIV-patients. It works by inhibiting HIV replication through a novel mechanism that has been shown in preclinical studies to result upon cessation of therapy (in contrast with all current treatments), in a long-lasting reduction of the viral load. ABX464 may become the critical element of a functional cure of HIV patients. In addition to robust ABX464 long-lasting efficacy, ABX464 treatment-resistant HIV mutants were not observed in chronic in vitro preclinical testing, suggesting that resistance may not develop in patients either.

"For the first time in the treatment of HIV-patients, with ABX464, there is a molecule which has the potential to deliver long-lasting reductions in the patients' viral loads after only a few weeks or months of treatment without development of resistance," commented Jean-Marc Steens, M.D., ABIVAX's Chief Medical Officer. "As a result of its attributes, its unique mode of action and the preclinical data obtained to date, many industry experts believe that ABX464 could play a central role in providing a functional cure for HIV patients."

ABX464 is an HIV antiviral drug with a mechanism of action that is linked to the inhibition of Rev, an HIV protein essential to the virus' replication. Rev plays a role in viral replication through: 1) ensuring that the viral transcript is not spliced in the nucleus of the cell; and 2) making certain that the unspliced transcript is exported from the nucleus into the cytoplasm. Inhibiting Rev is a completely new mechanism that has never before been explored for anti-HIV therapies. The major findings on ABX464 were published earlier this year in the peer-reviewed scientific journal Retrovirology: http://www.retrovirology.com/content/12/1/30/abstract.

ABX464 is the first candidate molecule to emerge from ABIVAX's proprietary antiviral "modulation of splicing" technological platform and proprietary chemical library. Developed in collaboration with the team of Professor Jamal Tazi at the CNRS in Montpellier, the molecule has been generated from an in-depth understanding of the processing of viral RNA within the human host cell.

ABX464 is in clinical development. At the end of 2014, after completing a phase Ia clinical trial in healthy volunteers, ABIVAX launched a Phase 1b pharmacokinetic study in 48 healthy volunteers in order to evaluate the impact of food in-take and the repeated administration of ABX464 on the pharmacokinetic properties as well as its tolerability and safety. This study has been finalized and the results are currently being analyzed.

Currently ongoing is the first trial of ABX464 in patients with HIV infection, a double-blind, placebo-controlled Phase IIa monotherapy dose-ranging trial. The study was launched in January 2015, and involves up to 80 treatment-naive patients (who never have received antiretroviral treatment), randomized into 10 dose groups of eight patients each (6 patients per group receiving daily ABX464 monotherapy for 3 weeks and 2 patients per group receiving placebo).

The primary endpoint of this study is to evaluate the safety and tolerability of ABX464 after repeated oral administrations in patients infected by HIV. Secondary endpoints will examine its pharmacokinetic profile and its impact as monotherapy (3 weeks only) on the viral load of patients infected with HIV over a 3-week treatment period.

Patients are currently being enrolled in Thailand and in Mauritius. This study is overseen by a Data Monitoring Board (DSMB) in charge of the safety aspects of the study, specifically authorizing each consecutive dose escalation. The DSMB has already reviewed safety data from the lower dose groups and authorized dose-escalation to the higher dose regimens, as planned in the study protocol. The preliminary results of this blinded study are expected to become available in January of 2016.

"The clinical safety data obtained on the first patients included in the 75 mg cohort in Thailand has provided us the reassurance we expected to recruit additional patients," stated Dr. Robert Murphy, Professor of Medicine and Biomedical Engineering, Northwestern University, Chicago. "We are thus encouraged to carry out the study as designed, with a gradual escalation of dosages, and look forward to clinical data."

In addition, ABIVAX is currently planning a second Phase IIa study in patients with HIV, to be initiated in France, Belgium and Spain. The double-blind trial will enroll 28 patients whose disease is controlled by treatment with boostered Darunavir. Patients will be randomized 3:1 to receive daily doses of either ABX464 at the highest tolerated dose from the currently ongoing study (21 patients) or placebo (7 patients). After 4 weeks of combination treatment, all therapies will be stopped, and the time to viral load rebound will be measured and compared between groups.

"We are convinced that this next trial, which is scheduled to start in the first quarter of 2016, is also an important study designed to clinically differentiate ABX464 from other anti-viral drugs," said Professor Hartmut J. Ehrlich, M.D., Chief Executive Officer of ABIVAX. "The ongoing Phase IIa study, which remains blinded, is focused on safety and identifying the best dose for further study. As such, not yet observing a significant reduction of viral load in treatment-naïve patients with ABX464 monotherapy for only 3 weeks would not slow down clinical development of ABX464 as long as safety is satisfactory." "With current HIV therapies, lifelong treatments with several drugs are needed. Cure is not achieved yet, and side effects, non-compliance, high costs and limited access to therapy are major health issues," continued Prof. Ehrlich.

"By contrast," Dr. Steens added, "our next Phase IIa study will explore the ability of ABX464 to induce a longer lasting therapeutic effect after treatment has been completed. The ability of ABX464 to exert exactly this type of sustained control of the viral load long after treatment has ended was convincingly demonstrated during its pre-clinical development."

HIV/AIDS was first identified in the United States around 1981. Since then the disease has spread and continues to constitute a global health issue that, according to the World Health Organization (WHO HIV/AIDS fact sheet n°360/November 2014), has claimed more than 39 million lives worldwide. In 2013, the World Health Organization estimated at 35 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.