ABIVAX's Novel Approach to Treat HIV Demonstrates Safety and Preliminary Anti-viral Activity in Phase IIa

ABX464 Data in HIV Treatment Naïve Patients Presented at CROI Supports Aim to Address Viral Rebound

Second Phase IIa Study to Evaluate lasting Viral Control with ABX464 Planned

Paris, France, February 25th, 2016 – 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 presented data from the Company's Phase IIa study demonstrating the safety and potent viral reduction capacity of ABX464 in treatment-naïve HIV positive patients. Data were presented by Dr. Jean-Marc Steens, M.D., Chief Medical Officer at ABIVAX, summarizing the findings published in an abstract entitled, *"Early Evidence of Antiviral Activity and Safety of ABX464 in HIV Treatment Naïve Patients"*, at the Conference for Retroviruses and Opportunistic Infections (CROI) in Boston, USA. ABX464 is an orally available therapeutic that blocks HIV replication through an entirely novel mechanism, i.e. the modulation of the biogenesis of viral RNA, and acts by targeting the Rev protein. ABIVAX believes that ABX464 could address the urgent need for long-term control of HIV rebound following the cessation of treatment.

"The positive results from this first Phase IIa study demonstrate the good safety and tolerability profile of ABX464, ABIVAX's drug candidate against HIV, as well as a dose-dependent viral load reduction," said Prof. Robert L. Murphy, M.D., Director at the Institute for Public Health and Medicine, Northwestern School of Medicine in Chicago, USA.

Study Details

The objective of the study presented at CROI was to evaluate the safety of ABX464 at ascending doses versus placebo in HIV-infected treatment naïve patients from Mauritius and Thailand. Patients were randomized into 5 successive cohorts of 8 patients each: 6 received 14 or 21 days of ABX464, and 2 received placebo. Successive cohorts received 25, 50, 75, 100 and 150 mg QD. The 25, 50 and 100 mg cohorts took the drug while fasting for 21 days; the 75 and 150 mg cohorts took the drug with food for 14 days. Viral load reduction of >0.5 log (>68%) was observed in 1/6 patients in the 75 mg cohort, 2/6 patients in the 100 mg cohort and 4/6 patients in the 150 mg cohort. There were no significant viral load changes in the 6 placebo patients from these cohorts. The only adverse events noted were nausea, vomiting and headache. All adverse events were grade 1 or 2 and all patients completed at least 14 days of treatment. The most common drug-related adverse events were headache, nausea, and vomiting. All occurred within the first 24 hours of dosing and diminished; no event was greater than Grade 2. Preliminary PK analysis suggest these events are related to Cmax.

ABX464 monotherapy showed dose related antiviral activity with 4-of-6 patients in the 150 mg dose group achieving 0.5 log10 reduction by Day 14. Preliminary PK analysis does not differentiate

responders versus non-responders. "*These data are very encouraging, and compel us to initiate a second Phase IIa trial*," said Prof. Hartmut Ehrlich, M.D., CEO of ABIVAX.

"*One of the primary objectives of a second Phase IIa trial will be to evaluate the lasting effect of ABX464 in the control of the viral replication following treatment cessation. In addition, specific focus will be placed on the HIV reservoirs, which are at the origin of all viral rebound*," said Dr. Steens. "*The second Phase IIa study with ABX464 will be conducted in combination with on-going therapies in currently treated patients. Details of the new study, which will be conducted in Belgium, France and Spain, will be communicated in the coming weeks*."

The abstract "*Early Evidence of Antiviral Activity and Safety of ABX464 in HIV Treatment Naïve Patients*" will be available on the CROI website at www.croiconference.org.

About ABX464

ABX464 is a first-in-class antiviral drug candidate for the treatment of patients with HIV-infection. It is an orally available small molecule that blocks HIV replication through an entirely novel mechanism, inhibition of Rev Activity. Preclinical data in humanized mice demonstrated that ABX464 monotherapy had an antiviral effect that was sustained following treatment interruption (Campos et al, Retrovirology 2015 12:30). A prior food-effect study demonstrated a three-fold increase in parent drug exposure when administered with food, without a significant impact on active glucuronide metabolite.

ABIVAX (www.abivax.com) 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. Follow us on Twitter @ABIVAX_

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