ABIVAX initiates clinical trial (ABX464-005) to evaluate the effect of ABX464 on HIV-reservoirs in HIV Patients

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- **First patient enrolled;**
- **The study seeks to unveil the biological mechanism of ABX464 behind the prolonged period before viral rebound occurs, seen in preclinical models;**
- **Initial results are expected in Q3 2017.**

Paris, March April 4th, 2017 at 6:00pm (CEST) – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases, announced today that the first patient has been enrolled, effectively launching the study, for which it has obtained regulatory and ethical clearance. This study in 24 HIV patients (ABX464-005) and 12 healthy volunteers (control arm) will examine the pharmacokinetics (PK) of ABX464 in HIV cellular reservoirs. ABIVAX believes ABX464 is a first-in-class drug candidate whose mechanism of action may lead to a functional cure for patients with HIV-infection (AIDS).

Given its goal for ABX464 to pursue a functional cure of patients with HIV-infection, ABIVAX focuses on studying the impact of the drug candidate in the various reservoir locations where the virus is hiding during effective antiretroviral therapy. These reservoirs include the blood, which is being evaluated in the almost completed study ABX464-004, and the gut, which is the main focus of ABX464-005.

The ABX464-005 study, which will be conducted at the Germans Trias i Pujol University Hospital Badalona (Barcelona, Spain), has enrolled the first patient today. These patients will receive ABX464 for 28 days in addition to their antiretroviral treatment. Rectal biopsies will be collected at certain intervals, allowing quantification of the viral load and the level of inflammation in this reservoir over time. The study may therefore provide a better understanding of the biological mechanism driving the long-term efficacy on the viral load rebound observed in preclinical models with ABX464. Initial results of the ABX464-005 study are expected in Q3 2017.

"Our understanding of this potential functional cure for HIV will benefit from this trial, which can demonstrate the prevention of viral replication originating from the HIV reservoir. Viral rebound is believed to originate in blood and tissue-resident macrophages and T-cells that have not been successfully targeted by existing anti-retroviral therapies" said Dr. Jean-Marc Steens, M.D., Chief Medical Officer of ABIVAX. "The ability of ABX464, in contrast to existing drugs, to act on already infected immune cells, like macrophages residing in the gut, will be further explored through specific ex vivo analyses of these reservoir cells, removed from patients in regular biopsies during the trial."

"By measuring the distribution and antiviral activity of ABX464 in rectal biopsies, this study will generate important data on how ABX464 impacts the HIV reservoir," addedProfessor Ian Mc Gowan, Professor of Medicine in the Division of Gastroenterology, Hepatology and Nutrition at the University of Pittsburgh School of Medicine and co-author of the study protocol. "Based on its unique mechanism of action, ABX464 has the potential to become a cornerstone to achieving a functional cure in patients with HIV."

ABX464, the first drug candidate from ABIVAX's proprietary antiviral platform, is an orally available small molecule therapeutic candidate that is currently in a second Phase IIa clinical trial in HIV-patients (ABX464-004). This ongoing placebo-controlled European trialis testing the effect of ABX464 on the HIV reservoir in monocytes and T-cells with integrated viral DNA in the blood of HIV patients treated with ABX464 in combination with established antiretroviral therapy. The effect on the reservoir may impact the time to viral rebound after treatment cessation.

Top-line results of the ABX464-004 study will be communicated on May 2, 2017.

The first Phase IIa study, the results of which were presented at CROI (the Conference on Retroviruses and Opportunistic Infections) in February 2016, showed a dose-dependent response of the viral load of treatment-naïve HIV-patients and a good safety and tolerability profile with no serious and or/severe adverse events.

ABX464 inhibits the HIV replication through a novel mechanism (i.e. the modulation of RNA splicing) that may not lead to the development of resistance by the HIV virus, and which may have a sustained effect in patients – as already has been demonstrated in preclinical testing.