Ongoing clinical development of ABX464: ABIVAX launches ABX464-004 study

First patient enrolled in second Phase IIa trial

Paris, May 30th, 2016 - ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing anti-viral therapies and immunotherapeutics for infectious diseases like HIV/AIDS and chronic hepatitis B (CHB), today announced that the first patient in the ABX464-004 study has been enrolled, effectively launching the second Phase IIa trial in HIV/AIDS patients with drug candidate ABX464. The first patient treatment in this trial is scheduled to take place at University Hospital Germans Trias i Pujol in Badalona, Barcelona, Spain. The trial will be conducted at clinical centers in Spain and Belgium, where all regulatory and ethics committees authorizations have been received, and in France where pending ethics committees approvals are expected imminently.

Prof. Bonaventura Clotet, Director of the IrsiCaixa AIDS Research Institute at the University Hospital Germans Trias i Pujol in Barcelona, Spain commented: "*We are very excited to enroll the first patient into this important clinical trial. The outcome of this study aims to provide a proof of concept that ABX464 could potentially be part of a functional cure for HIV*."

Study ABX464-004, the second Phase IIa trial conducted with ABX464, is designed to demonstrate the long-lasting effect of ABX464, which has been observed in preclinical studies. The study will enroll twenty-eight patients whose HIV infection is already fully controlled by boosted Darunavir. ABX464 will be administered to 21 of these patients in combination with their current drug regimen, while the remaining 7 patients will be given placebo in combination with their current therapy. After 28 days, all treatment will be discontinued and the study will then measure the time elapsed until the HIV virus reappears in the blood of the ABX464-treated patients and the control group. The efficacy endpoint of the study is the time to rebound of the viral load. This rebound will originate from the HIV reservoirs, which are not affected by current combination antiretroviral treatment. Preliminary results of this study are expected in Q4 2016.

An increase in the time to viral load rebound would constitute the first successful attempt at providing a functional cure for the HIV infection. Large-scale pivotal clinical studies of ABX464 will be required to confirm this hypothesis. These studies could begin by early 2017.

"*We are pleased to announce the start of this next clinical trial with ABX464*," said Prof. Hartmut Ehrlich, M.D., CEO of ABIVAX. "*This Phase IIa clinical trial is designed to test the promising preclinical data observed in an animal model, which showed evidence of long lasting control of viral load following cessation of ABX464 treatment. If confirmed in HIV patients in this study, such a long-lasting effect would differentiate ABX464 from all existing HIV therapies*."

Dr. Jean-Marc Steens, Chief Medical Officer at ABIVAX added: "*Study ABX464-004 comes on the heels of the first Phase IIa study with ABX464, which demonstrated good tolerability and viral load reduction in treatment naïve patients. We are eager to conduct this second Phase IIa study, which we believe could demonstrate the potential of ABX464 to provide a functional cure for HIV patients*."

ABX464 is an orally available small molecule therapeutic candidate that is currently in mid-stage clinical testing in HIV-patients. It works by inhibiting HIV replication through a novel mechanism (i.e. the modulation of RNA splicing) that may not be vulnerable to the development of resistance by the HIV virus, and may have a sustained effect in patients.

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