



## **ABIVAX obtains regulatory and ethics clearance in Spain to begin second Phase IIa clinical trial for ABX464 in HIV/AIDS patients**

### **Study to assess long-lasting effect of ABX464 on viral load reduction following conclusion of treatment in patients controlled by Darunavir/Ritonavir**

#### **Initial results expected in Q4 2016**

**Paris (France), April 19th 2016** - ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing antiviral therapies and therapeutic vaccines for infectious diseases like HIV/AIDS and chronic hepatitis B (CHB), today announced that its second Phase IIa study with ABX464, a first-in-class drug candidate for the treatment of patients with HIV/AIDS, has been approved by Regulatory and Ethics Committees in Spain. Additional approvals in Belgium and France are expected in the near future.

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. The first Phase IIa study, the results of which were presented at CROI (the Conference on Retroviruses and Opportunistic Infections) this past February, showed the following results for ABX464 used in monotherapy: 1) a dose-related response, with 4 out of 6 patients in the highest dose group (150mg) achieving 0.5 log<sup>10</sup> reduction by day 14; and 2) a good safety and tolerability profile, with no serious and/or severe adverse events. The second Phase IIa study is the next step in the planned development of this novel-acting antiretroviral drug.

With this approval, 28 patients will be enrolled in the second Phase IIa study and initial results are expected in Q4 2016. In addition to the Phase IIa clinical trials, large-scale clinical studies are expected to begin by early 2017.

Dr. Jean-Marc Steens, Chief Medical Officer at ABIVAX, commented, "Following the recent presentation of positive results from the first Phase IIa study in which ABX464 demonstrated good tolerability and viral load reduction in treatment naive patients, we are excited to begin this second Phase IIa study."

The Phase IIa clinical study will be conducted, subject to all necessary regulatory clearances, in 7 excellence sites in France, Belgium and Spain. One of the primary objectives of this study is to evaluate the long-lasting effect of ABX464 in the control of the viral replication following treatment interruption.

Prof. Hartmut J. Ehrlich, M.D., CEO of ABIVAX, added, "This approval further demonstrates the depth of Abivax's robust clinical development plan. This Phase IIa clinical trial is designed to



validate the promising preclinical data previously obtained with ABX464, especially the long-lasting control of viral load following the conclusion of treatment, and generate robust clinical evidence that could differentiate ABX464 from all existing HIV therapies.”

#### About ABIVAX ([www.ABIVAX.com](http://www.ABIVAX.com))

**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](http://www.abivax.com).

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