# ABIVAX's ABX464 Reduces HIV Reservoir in Blood in Second Phase 2a Clinical Trial

September 28, 2017

**ABX464 first ever drug candidate to show statistically significant (p<0.01) reduction in HIV viral reservoir**

**PARIS, Sept. 28, 2017 7:30 a.m. CEST** – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases using its unique technology platform, today announced top-line results from the first cohort of its Phase 2a trial, ABX464-005, demonstrating that ABX464 significantly reduced the HIV viral reservoir in blood in patients with HIV. The data confirm and extend the HIV reservoir reduction by ABX464 seen in ABIVAX's previous Phase 2a trial, ABX464-004.

*"These new data from the ABX464-005 study are very exciting and suggest that ABX464 could play a critical role in HIV cure or eradication strategies"* said Ian McGowan, 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. *"ABIVAX today reported data from the first cohort after treatment for 28 days. The second cohort, in which patients will be treated for three months, recently started recruiting patients and will begin to report data next year.The longer-term data will provide a better understanding of the potential for ABX464 to definitively induce a sustained viral remission."*

In the first cohort, 11 patients with HIV infection received 150mg ABX464 for 28 days in addition to their antiretroviral treatment. Blood samples and rectal biopsies were collected at pre-specified time intervals, allowing quantification of changes in the viral reservoir and mucosal inflammation over time.

Two patients discontinued the study due to grade 1/2 adverse events, which resolved upon a maximum of 6 days after ABX464 interruption.

Nine patients from the first cohort completed the study. Eight of these nine patients showed a decrease between day 0 and day 28 in HIV DNA in peripheral blood CD4+ T cells. The median for all nine patients decreased from 191 copies / million CD4+ T cells to 116 copies / million CD4 + T cells, resulting in a statistically significant decrease ($p<0.01$) in HIV DNA in CD4+ peripheral blood T cells. Because of low quality and quantity of cells isolated from the rectal biopsies, no reliable HIV DNA data from this tissue were obtained for this cohort.

Dr Jean-Marc Steens, M.D., chief medical officer of ABIVAX commented: *"Following the data from ABX464-004 showing the first evidence that ABX464 could reduce the HIV reservoir in the blood, the confirmation in ABX464-005, performed in a different laboratory, is an important validation of the potential for ABX464 leading towards a functional cure. This sensitive assay allowed us to not only confirm that ABX464 reduced HIV reservoir in blood, but also to show that the effect is more robust than previously observed. In this first cohort, the rectal biopsies did not yield enough HIV DNA to make an assessment of the viral reservoir. For the ongoing second cohort, we have made changes to the procedures to ensure that enough high quality viral DNA is available for the generation of the appropriate data."*

The second cohort of 12 patients will receive 50mg of ABX464 for three months in addition to their antiretroviral treatment. Similar to the first cohort, patients will undergo rectal biopsies at pre-specified intervals to quantify the change in viral load and level of inflammation over the three-month time period. The first patient of the second cohort was dosed at the Germans Trias i Pujol University Hospital Badalona in Barcelona, Spain. Initial results of the second cohort are expected in the second quarter of 2018.

The results of this study are being submitted to major international HIV conferences.

*"Before we received these data we had an exciting trend, now we have solid evidence for the reduction of the HIV reservoir in the blood"* said Prof. Hartmut Ehrlich, M.D., CEO of ABIVAX. *"The new findings of the ABVX-005 study affirm our commitment and deepen the responsibility we have towards all HIV patients and the HIV community in driving this unique compound forward as rapidly as possible," he added. "Clearly, more research and clinical evidence are needed to achieve our goal of sustained viral remission, and we are going to strengthen the development of ABX464 by expanding our clinical program."*

**WEBCAST PRESENTATION**

ABIVAX's senior management will host a webcast presentation on September 28 th, 2017 at 4:00 pm CET (Paris time), to present and discuss the new data. The webcast presentation can be accessed via the following link: https://edge.media-server.com/m6/p/fkrugv6w, and attendees can log on using the following telephone information:

**Confirmation Code: 3589226**

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| Participants, Local - Paris, France : | +33(0)1 76 77 22 28 |
| Participants, Local - New York, United States of America: | +1646 254 3360 |
| Participants, Local - London, United Kingdom: | +44(0)20 3427 1911 |

*The UK number is an international number and can be accessed from any country*

**About ABX464**

ABX464, the first drug candidate from ABIVAX' proprietary antiviral platform, inhibits the HIV replication through a novel mechanism (i.e. the modulation of RNA biogenesis) 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. ABX464 is an orally available small molecule therapeutic candidate. Earlier Phase IIa studies, the results of which were presented at CROI (the Conference on Retroviruses and Opportunistic Infections) in February 2016 and at the IAS (International AIDS Society) Conference in July 2017, showed a dose-dependent response of the viral load of treatment-naïve HIV-patients and a first

reduction of the HIV reservoir in the blood of chronically infected, well suppressed HIV patients, respectively. Having been administered to >150 volunteers and patients, ABX464 has a good safety and tolerability profile with no serious and or/severe adverse events.