



ABIVAX Presents New Data on ABX464 Mechanism of Action at 16th European Meeting on HIV & Hepatitis

May 31, 2018

- Latest findings reveal ABX464's mechanism of action in HIV and ulcerative colitis
- Binding of ABX464 to Cap Binding Complex (CBC) enhances RNA splicing of viral and non-translated human RNA, mediating antiviral and anti-inflammatory effects
- ABIVAX Chief Medical Officer invited to deliver a plenary lecture on ABX464 clinical development

PARIS, May 31, 2018, 8:00 a.m. CEST – ABIVAX (Euronext Paris: FR0012333284 – ABVX), a biotechnology company harnessing the immune system to develop a functional cure for HIV as well as treatments for inflammatory/autoimmune diseases and cancer, today unveiled new data characterizing the mechanism of action of its lead Phase 2 clinical candidate ABX464. The data are being presented at the 16th European Meeting on HIV & Hepatitis - Treatment Strategies & Antiviral Drug Resistance, being held at the Roma Eventi – Fontana di Trevi Conference Centre in Rome, Italy from May 30 to June 1, 2018. The company will present the mechanism of action of ABX464, in both HIV and ulcerative colitis, as well as provide an update on the progress of clinical trials of ABX464 in HIV.

New data show that ABX464 binds to the cap binding complex (CBC) and thereby enhances the splicing of two types of RNA: 1) a segment of viral RNA which the HIV virus requires for replication, thus inhibiting replication; and 2) a long non-coding human RNA, which, upon splicing, results in increased expression of miR124, a small microRNA with potent anti-inflammatory properties. As the increased splicing was shown to produce a novel viral RNA species, this may trigger immune recognition of HIV-infected cells.

"These latest results explain why ABX464 could be delivering a dual anti-HIV effect via its antiviral and anti-inflammatory properties. In addition, taken together with the observed presence of a new RNA species, they provide a compelling rationale for our demonstration, for the first time in the HIV-field, of a reduction of the HIV reservoir in our previous clinical trials," said **Professor Hartmut Ehrlich, MD, Chief Executive Officer of Abivax**. *"Triggering miR124 expression via ABX464 treatment is a novel and interesting mechanism that we are just beginning to understand. Upregulation of miR124 has been identified in research by multiple leading scientists as an exciting therapeutic target, with potential for treating multiple indications where inflammation plays a role. These data further support the rationale for our ongoing Phase 2a proof-of-concept study of ABX464 to treat ulcerative colitis, and support studies in additional indications."*

The presentation by **Prof. Jamal Tazi, Ph.D.**, Director at the CNRS (National Centre for Scientific Research) in Montpellier, France and Member of ABIVAX's Scientific Advisory Board, entitled "ABX464, by binding to the CBC 80/20 complex, enhances pre-mRNA splicing, resulting in the generation of novel HIV-derived RNA species and in increased expression of the anti-inflammatory miR-124", further clarifies the mechanism of action of ABX464 in both HIV and in ulcerative colitis.

Prof. Tazi will present deep sequencing data showing that enhanced splicing generates one form of new spliced viral RNA that could potentially trigger immune recognition of HIV-infected cells in the HIV reservoirs. Data presented will also demonstrate that ABX464 enhanced the expression and splicing of a single long non-coding human RNA generates the anti-inflammatory miR124 both ex vivo and in HIV patients. Given the critical role of miR124 up-regulation in inflammation, and the ability of ABX464 to produce both novel viral RNA and miR-124 by enhanced splicing, these results provide evidence that targeting of the CBC by ABX464 could be a safe approach to achieve a functional HIV cure as well as a means to treat inflammatory diseases.

Dr. Jean-Marc Steens, Chief Medical Officer at ABIVAX, will deliver a plenary presentation on the clinical development of ABX464, candidate in Phase II for HIV cure. His review will cover the two completed Phase 2a clinical studies (ABX464-004 and the first cohort of ABX464-005), which independently confirmed that ABX464 can reduce HIV DNA containing reservoir cells up to 50% after only 28 days of administration with antiretrovirals. Dr. Steens will also discuss the design of two additional studies: the ongoing second cohort of ABX464-005, in which patients are being treated with ABX464 for 3 months with top-line data expected later this summer, and an upcoming Phase 2b study to be conducted in the US and in Europe, with clinical trial submission planned for the second half of 2018.

Presentation Details:

- Title: ABX464, by binding to the CBC 80/20 complex, enhances pre-mRNA splicing, resulting in the generation of novel HIV-derived RNA species and in increased expression of the anti-inflammatory miR-124
- Date/Time: 31 May, 2018 at 10:00 am CET

- Session: Poster Session 2

- Location: Roma Eventi, Rome, Italy

Plenary Lecture Details:

- Title: Clinical Development of ABX464 , drug candidate for HIV Cure

- Date/Time: 1 June, 2018 at 9:30 am CET

- Session: Session 7 - What's in the pipeline?

- Location: Roma Eventi, Rome, Italy