ABIVAX provides update on clinical development program for ABX464 for functional cure of patients with HIV-infection

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- **Ongoing second phase IIa treatment interruption study (ABX464-004) now expected to deliver top-line results in April 2017**
- **New clinical trial, ABX464-005, studying the effect of ABX464 on the HIV reservoir submitted for regulatory authorization**
- **New pre-clinical data suggest strong anti-inflammatory activity of ABX464: Proof-of-concept clinical study in Inflammatory Bowel Disease planned for 2017**

Paris, December 6th, 2016 – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral disease, today provides a clinical update on the clinical development program for ABX464, ABIVAX's first-in-class drug candidate for achieving a functional cure in patients with HIV/AIDS.

Given the current pace of recruitment, which is slower than expected, ABIVAX anticipates to communicate the top-line results of the ongoing Phase IIa study (ABX464-004) in April 2017, which translates into a delay of four months compared with the initial estimate. This phase IIa clinical trial is currently enrolling patients in Spain, Belgium and France. One of the co-primary endpoints of the study is the long-lasting effect of ABX464 in maintaining a low viral load in the blood of infected patients, which were treated with an established antiretroviral therapy and ABX464 or placebo.

On top of the ongoing ABX464-004 Phase IIa study, ABIVAX recently requested regulatory and ethics committee approval for a new study, which is a compartmental pharmacokinetics (PK) clinical study (ABX464-005). In this study, HIV infected patients will receive ABX464 for 28 days in addition to their antiretroviral treatment. Rectal biopsies will be collected at different intervals, allowing the effect of ABX464 on the reservoir of HIV (which primarily resides in the gut) to be examined. This study, which will be conducted at the Germans Trias i Pujol University Hospital Badalona (Barcelona, Spain) will quantify the viral load and level of inflammation in the reservoir over time and, therefore, will provide a better understanding of the long-term efficacy observed in pre-clinical models with ABX464. Following receipt of the appropriate regulatory approvals, ABIVAX expects to initiate this study in the first half of 2017.

"This new clinical study is important for our understanding of the effect of ABX464 on the HIV reservoir, which is the source of viral rebound following the conclusion of anti-retroviral treatment," said Dr. Jean-Marc Steens, Chief Medical Officer of ABIVAX. "The successful development of a functional cure for HIV will benefit from demonstrating the prevention of viral replication originating from the HIV reservoir."

Finally, new preclinical data generated with ABX464 demonstrate a strong anti-inflammatory effect of the compound. In macrophages, this effect was shown to be mediated by a 50-fold increase of the expression of IL-22, a cytokine known as a potent suppressor of inflammatory processes. Inflammation is a cornerstone of the pathologies observed, not only in HIV, but also in a number of other diseases, such as inflammatory bowel disease (IBD, including ulcerative colitis and Crohn's disease). When evaluated in a mouse model of IBD, ABX464 demonstrated a long-lasting effect in preventing the typical symptoms of inflammatory colitis, including histological changes. Based on these encouraging results, the company intends to launch a proof of concept clinical study in patients with IBD in 2017.

"These new data on the long-lasting anti-inflammatory effect of ABX464 are very promising, as they indicate the potential of our lead development compound to modulate important disease parameters in both HIV and IBD. We look forward to endeavoring to replicate these results in clinical trials," said Prof. Dr. Hartmut Ehrlich, CEO of ABIVAX.

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