Analysis of ongoing ABX203 Phase IIb/III trial in chronic hepatitis B virus infection shows good safety, but primary endpoint of study is unlikely to be reached

- Post---treatment monitoring of the patients will be continued as per protocol in order to provide additional insight on clinical trial outcomes and secondary endpoints
- Future development of ABX203 under review, including the addition of an adjuvant, new administration schedules and therapeutic combinations
- Ongoing anti---HIV ABX464 Phase IIa trial progressing well
- Four additional product candidates in pipeline

Paris, June 17, 2016 --- ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative company developing anti---viral therapies and immunotherapeutics for infectious diseases like HIV/AIDS, chronic hepatitis B (CHB), chikungunya, ebola as well as an adjuvant to enhance the immune response, today announced that a futility analysis on the primary end---point of its ABX203---002 trial, a Phase IIb/III trial of ABX203 in CHB patients, determined that the trial is unlikely to reach its primary endpoint.

The ABX203---002 study is an open---label, randomized, comparative study designed to assess the efficacy of ABX203 to maintain control of the hepatitis B virus after cessation of nucleotide analogs (NUCs), in particular in controlling viral load for a much longer period of time when compared to current treatment options. This study is ongoing in seven Asian/Pacific countries (Taiwan, Hong---Kong, Thailand, Singapore, South Korea, Australia and New---Zealand). In this large scale controlled and randomized study, where 276 subjects were enrolled as of September 2015, one group of patients received ABX203 for 24 weeks, in addition to the current standard of care (nucleoside analogues, NUCs). All therapy was stopped after 24 weeks, and these patients are evaluated against a control group receiving NUCs only. The study's primary efficacy endpoint is the percentage of subjects with viral load <40 IU/mL at week 48, i.e 24 weeks after the treatment with ABX203 has been completed.

An unscheduled futility analysis was initiated because of a recent increase in the patients' drop out rate related to viral escape. A futility analysis is conducted during an ongoing clinical trial to describe the probability of a study to reach its primary endpoint. The result of this analysis shows that a positive outcome of the study regarding its primary endpoint is unlikely.

The Data Safety and Monitoring Board (DSMB) of study ABX203---002 was convened. The DSMB has recognized the good safety profile of ABX203 and recommended that the study should continue as per protocol, to monitor patients 24 weeks post---treatment in order to continue to assess their viral load and to have a comprehensive view of the secondary endpoints. Investigators, health authorities and patients are being informed of the conclusions of the DSMB.

In a previous Phase II study, with a different design and carried out in Asia, treatment---naïve patients with chronic hepatitis B were administered ABX203 as monotherapy. That study established a significantly longer period to viral rebound as compared to patients receiving Peg---Interferon Alpha.

The future development of ABX203 is under review, including the usefulness of an adjuvant boosting the response to this immunotherapy, as well as new administration schedules and therapeutic combinations that may be evaluated via other preclinical and, potentially, clinical testing.

The ABIVAX portfolio includes other product candidates that are progressing to plan. ABX464, which is in development for the treatment of HIV, recently started a second Phase IIa trial after demonstrating its safety and anti---viral properties in the first Phase IIa study earlier this year. The ongoing placebo controlled Phase IIa study ABX464---004 is designed to demonstrate the long---lasting effect of ABX464, which has been observed in preclinical studies. The study is enrolling 28 patients whose HIV infection is already fully controlled by boosted Darunavir; 21 of the patients will be administered ABX464, and seven will receive placebo in addition to their current antiretroviral therapy. After 28 days, all treatment will be discontinued and the primary endpoint will compare the time elapsed until the HIV viral load rebounds in the ABX464---treated patients and the placebo control group. The primary efficacy endpoint measures time to rebound of the viral load. Such rebound is believed to originate from the HIV reservoirs, which are not affected by current combination antiretroviral treatments. Preliminary results of this study are expected in Q4 2016.

ABIVAX is leveraging three distinct drug discovery platforms, outlined below:

1) A unique and proprietary anti---viral discovery platform, which ABIVAX used to identify ABX464. ABIVAX also is currently optimizing two small molecule therapeutic candidates, discovered using the platform, which have potential for treatment of chikungunya. Additionally, the anti---viral discovery platform is currently being used to generate additional new chemical entities to treat dengue, RSV and other infectious diseases.

2) An adjuvant discovery platform, used to identify lead adjuvant ABX196, an immune enhancer for infectious diseases and oncology.

3) A hyperimmune platform, currently focused on discovering a novel approach to treating Ebola.

Further details regarding these discovery platforms and the exciting molecules that they have produced will be communicated in an R&D day during the second half of this year.

ABIVAX senior management will host a conference call to discuss these developments today at 7PM CET/1PM EDT. Following are the dial---in details.

From France:	+33 (0)1 76 77 22 31
From Germany:	+49 (0)69 2222 10626
From the United Kingdom:	+44 (0)203 427 1916
From the United States:	+1 212 444 0895
Pass code:	**8743808**

A replay of the conference call will be available for seven days by dialing the following numbers:

France:	+33 (0)1 74 20 28 00
Germany:	+49 (0)89 2030 3201

United Kingdom: +44 (0)20 3427 0598
United States: +1 347 366 9565

Replay Passcode: 8743808

ABIVAX is an innovative biotechnology company in the discovery and development 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. Follow us on Twitter @ABIVAX

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