



ABIVAX reports healthy volunteers Phase I data for ABX464

Very good safety and pharmacokinetic data permit multiple phase II studies in HIV patients

First Phase IIa trial in HIV patients ongoing

Paris, France, November 30th 2015 – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an emerging leader in developing and commercializing anti-viral drugs and therapeutic vaccines for diseases like HIV/AIDS and chronic hepatitis B (CHB), today announced positive results of first clinical evaluation of ABX464 in healthy volunteers for safety and pharmacokinetics. ABX464 is a once-daily orally available first-in-class small molecule drug candidate that inhibits HIV replication through an entirely new mechanism. A first Phase IIa clinical trial of ABX464 in naive patients infected with HIV was launched in 2015 with results expected in January 2016. A second Phase IIa in HIV patients already treated by standard therapy is planned to start in the near future.

“We are very pleased that ABX464 demonstrated good safety and tolerability, as well as a pharmacokinetic profile that is consistent with the high standards required for a new drug to treat HIV,” said Jean-Marc Steens M.D., Chief Medical Officer of ABIVAX. *“These trials encouraged us to begin the ongoing monotherapy Phase IIa clinical trial in untreated HIV patients earlier this year, which will report data in January 2016 and plan the second Phase IIa study in HIV patients previously treated with standard HIV therapy.”*

«Thanks to its unique mechanism, ABX464 could become the first therapeutic capable of delivering robust, long-lasting reductions in HIV-patients’ viral loads, without development of resistance, » said Professor Hartmut Ehrlich, M.D., CEO of Abivax. *«As a result, we believe ABX464 could become the central element of a functional HIV cure strategy. »*

ABIVAX has conducted two phase 1 clinical trials in a total of 72 healthy volunteers: first, a single ascending dose (SAD) study focusing on the pharmacokinetics and tolerability of ABX464; and, second, a study to evaluate the effect of repeated dosing and of food intake on the safety and bioavailability of ABX464.

The SAD study was an open-label study performed in 24 healthy male subjects to determine pharmacokinetic and safety profiles of 4 single ascending oral doses of ABX464 (50, 100, 150 and 200 mg) under fasting conditions. A linear dose-related absorption and bioavailability of ABX464 was observed up to the 150 mg dose group, with a plateau (i.e. no additional bioavailability) observed at the 200mg dose.

Pharmacokinetic analyses showed that ABX464 is rapidly metabolized into ABX464-N-glucuronide in humans. This metabolite has a long half-life ($t_{1/2}$) of 3-4 days in humans and also has been demonstrated to be functionally active against HIV.

ABX464 demonstrated good safety and was generally well tolerated. Adverse events were



infrequent and observed primarily at the highest doses, consisting of mild to moderate headache and nausea/emesis. No serious adverse events related to ABX464 were observed in the study.

The food effect study included a total of 48 healthy volunteers:

- Group 1 (24 subjects): A single oral dose of 50 mg ABX464 was administered in fed and fasted conditions separated by wash-out of 45 days. In this cross-over design, patients were their own control.
- Group 2 (24 subjects): 50 mg ABX464 were administered orally every 3 days over 10 days in fasted or fed conditions.
 - 12 subjects received 4 administrations of 50 mg ABX 464 during fasted conditions
 - 12 subjects received 4 administrations of 50 mg ABX 464 during fed conditions

ABX464 was generally well tolerated and no significant adverse events related to ABX464 were reported. A 3-fold increased bioavailability, with a marginal effect on the glucuronide metabolite, was observed in Group 1 during fed conditions. The same pattern of 3-fold increased bioavailability and insignificant metabolite modification were observed in Group 2 after repeated administration of ABX464.

Based on these results, ABIVAX is actively continuing clinical development of ABX464 in patients, administered in fed conditions, which is the most common practice for marketed HIV therapies. More detailed results from both studies are being submitted to peer reviewed journals for publication.

This first trial of ABX464 in patients with HIV infection is a double-blind, placebo-controlled Phase IIa monotherapy dose-ranging trial. The study was launched in 2015, and involves up to 80 treatment-naive patients (who never have received anti-retroviral treatment), randomized into 10 dose groups of eight patients each (6 patients per group receiving daily ABX464 monotherapy for 3 weeks and 2 patients per group receiving placebo).

The primary endpoint of this study is to evaluate the safety and tolerability of ABX464 after repeated oral administrations in patients infected by HIV. Secondary endpoints will examine its pharmacokinetic profile and its impact as monotherapy on the viral load of patients infected with HIV over a short 3-week treatment period.

Patients are currently being enrolled in Thailand and in Mauritius. This study is overseen by a Data Monitoring Board (DSMB) in charge of the safety aspects of the study, specifically authorizing each consecutive dose escalation. The DSMB has already reviewed safety data from the lower dose groups and authorized dose-escalation to the higher dose regimens, as planned in the study protocol. The high-level results of this blinded study are expected to become available in January of 2016.

In addition, ABIVAX is currently planning a second Phase IIa study in patients with HIV, to be initiated in France, Belgium and Spain. The double-blind trial will enroll 28 patients whose disease is controlled by treatment with boosted Darunavir. Patients will be randomized 3:1 to receive daily doses of either ABX464 at the highest tolerated dose from the currently ongoing study (21 patients) or placebo (7 patients). After 4 weeks of combination treatment, all therapies will be stopped, and the time to viral load rebound will be measured and compared between groups.



HIV/AIDS was first identified in the United States around 1981. Since then the disease has spread and continues to constitute a global health issue that, according to the World Health Organization (WHO HIV/AIDS fact sheet n°360/November 2014), has claimed more than 39 million lives worldwide. In 2013, the World Health Organization estimated at 35 million the number of people still living with the virus, with an additional 2 million becoming newly infected each year. Treated with anti-retroviral therapy HIV/AIDS has become a chronic infection but remains a deadly disease that places a significant burden on healthcare resources. ABIVAX estimates the total worldwide cost for anti-HIV drugs to be around \$18 billion annually.

ABIVAX (www.abivax.com) is an emerging global leader in the discovery, development and commercialization of anti-viral therapeutics and 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 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.

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