Phase I Clinical Data of ABX464, ABIVAX's First-in-Class anti-HIV Drug, Published in Two Articles in Peer-Reviewed Journals

February 2, 2017

Paris, February 2nd, 2017 at 6:00pm (CET) – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases, announced today that the previously disclosed results of its two Phase I trials with ABX464 in healthy volunteers have now been published in peer-reviewed journals: Journal of Antimicrobial Chemotherapy and, separately, Antimicrobial Agents and Chemotherapy.

"We are pleased with the good safety and pharmacokinetic properties of ABX464, which are now published in peer-reviewed journals," said Jean-Marc Steens, MD, Chief Medical Officer of ABIVAX. "ABX464 is currently completing a Phase IIa clinical study to establish its long-acting activity in reducing the viral load in patients, in order to confirm in humans the long-lasting preclinical efficacy we previously observed. ABX464 also is expected to enter into a Phase IIa proof of concept study in inflammatory bowel disease this year."

ABX464, originating from ABIVAX' unique and proprietary antiviral library of small molecules targeting RNA biogenesis, is a novel, first-in-class molecule with unique properties and mode of action. Specifically, it inhibits the HIV REV protein, which is critical for viral replication. ABX464 has not only been demonstrated to inhibit viral replication in vitro and in vivo, but also to induce a long-lasting reduction of viral load following treatment interruption in a preclinical HIV model. As a result, ABX464 may be the first of a new class of anti-retroviral drugs, and could become a key component to developing a functional cure for patients.

Moreover, ABX464 has been shown to stimulate the expression of anti-inflammatory molecules (IL-22 and miR124) in immune cells in preclinical testing. For example, ABX464 was recently shown to protect mice from the lethal effects of DSS (Dextrane Sulfate Sodium), a substance inducing severe colitis. Based on these results, ABX464 will enter into a Phase II proof-of-concept (POC) study in inflammatory bowel disease later this year.

The published Phase I studies were conducted in 24 and 48 healthy volunteers, respectively. They demonstrated that, following oral administration, ABX464 was well absorbed by the intestine and well tolerated by the healthy volunteers. The administration of ABX464 with food resulted in favorable pharmacokinetic properties at the anticipated therapeutic doses.

ABX464 was rapidly and substantially metabolised into ABX464-N-Glucoronide. The Cmax (maximal concentration) of the metabolite was observed approximately 4h post-dose and was about 160-fold higher than that of the parent with a much longer half-life (90-110h). It has been demonstrated in vitro that the metabolite was able to inhibit HIV replication in macrophage culture with the same IC50 as the parent drug (Ref. Campos N, Myburgh R, Garcel A, Vautrin A, Lapasset L, Nadal ES, et al. Long lasting control of viral rebound with a new drug ABX464 targeting Rev – mediated viral RNA biogenesis. Retrovirology 2015; 12:1-15)

For more details please see:

- Journal of Antimicrobial Chemotherapy : Pharmacokinetics and tolerability of ABX464, a novel first-in-class compound to treat HIV infection, in healthy HIV-uninfected subjects https://www.ncbi.nlm.nih.gov/pubmed/27999038

- Antimicrobial Agents and Chemotherapy : Randomized Trial of Food Effect on Pharmacokinetic Parameters of ABX464 Administered Orally to Healthy Male Subjects https://www.ncbi.nlm.nih.gov/pubmed/27799203