



## **New Experimental Data on Anti-inflammatory Effects of ABX464, ABIVAX's First-in-Class Drug Candidate to Achieve Functional Cure in HIV-Patients, Published in Nature Scientific Reports**

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### **ABX464 Shown to Dampen Intestinal Inflammation by Triggering IL-22 Production in Activated Macrophages Resulting Anti-inflammatory Effect Protected Mice from a Lethal Model of Colitis, With Full Preservation of Bowel Structure**

#### **Proof-of-Concept Phase 2 Trial in IBD (Ulcerative Colitis) Planned to Begin in 2H 2017**

**Paris, July 12, 2017 at 7:00 am (CET)** – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases, today announced the publication of a paper on its lead product candidate ABX464 in the July 7, 2017 online edition of Nature Scientific Reports. The paper entitled “The Anti-HIV Candidate ABX464 Dampens Intestinal Inflammation by Triggering IL-22 Production in Activated Macrophages”, authored by Prof. Jamal Tazi, et al., summarizes the experiments that explored the mechanisms by which ABX464 exerts its anti-inflammatory properties, as well as implications for potential therapeutic use in inflammatory bowel disease (“IBD”).

“We are pleased to see publication of our data which give us valuable insight into ABX464’s activity in HIV and also supports its potential role as a novel and differentiated treatment for inflammatory bowel disease and especially ulcerative colitis,” said Prof. Hartmut J. Ehrlich, M.D., CEO of ABIVAX and coauthor of the publication. “Based on these encouraging results, ABIVAX is initiating a Phase 2a proof of concept clinical study in patients with ulcerative colitis during the second half of 2017.”

ABX464, originating from ABIVAX’s 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 been demonstrated to induce a long-lasting reduction of viral load following treatment interruption in a preclinical HIV model. Importantly, in a recently completed Phase 2a clinical trial, ABX464 was also shown to demonstrate the first pharmacological reduction of the HIV reservoir (i.e. the human immune cells with integrated viral genetic material that are not affected by current antiretroviral therapy leading to viral rebound as soon as treatment is stopped) in peripheral blood mononuclear cells (“PBMCs”) in HIV-patients. As a result, ABX464 could become a key component for a functional cure of HIV-patients.

The new publication summarizes the in-vitro and in-vivo findings with ABX464 on reducing inflammation, as well as potential therapeutic implications. ABX464 was shown to stimulate the expression of the anti-inflammatory cytokine IL-22 in macrophages in preclinical testing. In addition, ABX464 was shown to protect mice from the lethal effects of dextran sulfate sodium (“DSS”), which is an established animal model for experimental colitis. ABX464 treatment was not only critical for the survival of DSS-challenged mice, but also fully protected the histological structure of the murine intestine against changes induced by severe inflammation. RNA profiling analysis showed that ABX464 induced the expression of IL-22, and this was demonstrated both in DSS-challenged mice as well as in in vitro studies of LPS-stimulated bone marrow-derived macrophages. IL-22 is a cytokine that regulates tissue repair and recovery. The protective effect of ABX464 in these mice was substantially reduced by the simultaneous administration of antibodies to IL-22. ABX464 also showed a long-term protection against prolonged DSS-exposure after drug cessation. Furthermore, ABX464 reduced the colonic production of the pro-inflammatory cytokines IL-6 and TNF $\alpha$  and also the chemoattractant MCP-1.

“The results presented in this paper show for the first time that ABX464 specifically acts on the immune system to attenuate mucosal disease induced by DSS”, said Jamal Tazi, Ph.D., inventor of ABX464, Professor at the CNRS in Montpellier, member of the ABIVAX executive committee and senior author of the paper. “ABX464’s ability to dampen intestinal inflammation in DSS-mice was clearly demonstrated. Additionally, its ability to reduce the inflammatory cytokines IL-6 and TNF $\alpha$  and induce the expression of IL-22 leading to tissue repair, and show long-lasting protective effects, is very promising.”

“These results are encouraging and potentially meaningful for patients with IBD, a debilitating and potentially life-threatening disease. Given the limitations with many existing treatment options for IBD, an orally-available treatment, such as ABX464, that has the ability to reduce inflammation and promote tissue repair would represent a significant step forward in the treatment of these patients,” said Dr. Ian McGowan, a Professor of Medicine in the Division of Gastroenterology, Hepatology and Nutrition at the University of Pittsburgh School of Medicine.

Please find the Nature Scientific Reports article using the following link:

<https://www.nature.com/search?journal=srep&order=relevance&q=tazi>