

Abivax Completes Dosing in Phase 2a Proof-of-Concept Clinical Trial of ABX464 in Ulcerative Colitis (ABX464-101)

Top-line results expected in September 2018

PARIS, July 19, 2018, 8:00 a.m. CEST – ABIVAX (Euronext Paris: FR0012333284 – ABVX), a biotechnology company harnessing the immune system to develop a functional cure for HIV, as well as treatments for inflammatory/autoimmune diseases and cancer, today announced the completion of dosing in its Phase 2a clinical trial ABX464-101 in 32 patients with moderate-to-severe ulcerative colitis (UC). Patients will be monitored and data collected and analyzed by investigators according to trial protocol. Top-line results are expected in September of 2018.

“Because of its mechanism, which has demonstrated powerful anti-inflammatory properties, ABX464 may have the potential to bring significant clinical benefit to patients struggling with inflammatory bowel diseases like UC so we are eager to see the top-line data from this study and continue development,” said **Prof. Dr. Hartmut Ehrlich, M.D., Chief Executive Officer at ABIVAX**. *“We’re on track to report top-line results from this trial in September of 2018 and, if positive, move ABX464 rapidly into a Phase 2b clinical trial.”*

ABX464-101 is a randomized, double-blind, placebo-controlled Phase 2a proof-of-concept study evaluating the safety and efficacy of ABX464 50mg given once daily versus placebo for two months in subjects with moderate-to-severe active ulcerative colitis who have failed or are intolerant to immunomodulators, anti-TNF α , vedolizumab and/or corticosteroids. This clinical study is being conducted in 17 centers in seven European countries: Belgium, France, Germany, Austria, Hungary, Poland and Czech Republic. As of today, all of the 32 recruited patients, randomized 2:1 to receive ABX464 or placebo, have completed the study and will undergo a one-month follow-up period. The study employs state-of-the art technologies for monitoring potential treatment effects, including numerical recording of the colonoscopies with centralized reading.

Prof. Dr. Severine Vermeire, M.D., Head of the IBD center at the University Hospitals Leuven, Belgium and Principal Investigator of the study, said: *“Even with the introduction of biologic treatments in recent years, there is still a largely unmet need as too many patients never respond or stop responding to biologics. It is encouraging that the majority of patients in the trial (21/32) agreed to enroll into the one year open-label extension study with ABX464, ABX464-102, which will provide us with important long-term safety and maintenance efficacy data.”*

ABX464-102 is a 12-month open-label follow-up study for patients who complete ABX464-101.

About ABX464

The rationale for the ABX464-101 study was based on preclinical data demonstrating that ABX464 had a strong anti-inflammatory effect. In macrophages, this effect was shown to be mediated by a 50-fold increase of IL-22 expression, a cytokine known as a potent suppressor of inflammatory processes, and a ten-fold increase of miR124 in peripheral blood mononuclear cells (PBMCs). miR124 is a micro-RNA with potent anti-inflammatory properties and has recently been described as a tumor suppressor gene.



Inflammation is a cornerstone of IBD, particularly in 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 changes¹.

About Ulcerative Colitis

Ulcerative colitis is a debilitating inflammatory bowel disease in adults and children, with limited therapeutic management options for many patients. It is estimated that close to 1 million patients with ulcerative colitis live in the United States, and global pharmaceutical sales for this disease are estimated to be around \$5.7 billion in 2017.

About ABIVAX (www.abivax.com)

ABIVAX is mobilizing the body's natural immune machinery to treat patients with viral infections, autoimmune diseases and cancer. A clinical-stage company, ABIVAX leverages its antiviral and immune enhancing platforms to optimize candidates to cure HIV and treat inflammatory bowel diseases, as well as liver cancer. ABIVAX is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at www.abivax.com/en. Follow us on Twitter @ABIVAX_

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¹ K Chebli et al., The Anti-HIV Candidate ABX464 Dampens Intestinal Inflammation by Triggering IL-22 Production in Activated Macrophages. Nature Scientific Reports 2017, DOI:10.1038/s41598-017-04071-3