Abivax Completes Enrolment of Phase IIa Clinical Trial of ABX464 to Treat Patients with Ulcerative Colitis

May 14, 2018

- **Top-line data in autumn 2018**
- **Ten patients already enrolled in one year open-label extension**

PARIS, May 14, 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 announces the completion of enrollment of its Phase IIA clinical trial ABX464-101 in 30 patients with moderate-to-severe ulcerative colitis.

"ABIVAX is very pleased to announce the completion of enrolment in this first clinical trial exploring ABX464 for treatment of inflammatory indications," said Prof. Dr. Hartmut Ehrlich, M.D., chief executive officer at ABIVAX. *"I would like to highlight the outstanding enthusiasm and dedication of Prof. Dr. Severine Vermeire, M.D., the Principal Investigator of this multinational trial and past president of ECCO (European Crohn'd and Colitis Organization), and thank the clinical trial sites, which kept recruitment on target, allowing us to report the top-line results from this important clinical trial in the autumn of this year,"* added Dr. Ehrlich.

ABX464-101 is a randomized, double-blind, placebo-controlled clinical trial (Phase 2a proof-of-concept study) aimed at evaluating the safety and efficacy of ABX464 50 mg 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-TNFα, 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, 30 out of the planned 30 patients have been randomized 2:1 to receive ABX464 or placebo, respectively. The study employs state-of-the art technologies for monitoring potential treatment effects, including numerical recording of the colonoscopies with centralized reading.

ABX464-102 is a 12 months open label follow-up study for patients who completed ABX464-101, and 10 patients are already recruited into this clinical trial as of today.

The rationale for the ABX464-101 study was derived from encouraging preclinical data, which demonstrated ABX464 had a strong anti-inflammatory effect. In macrophages, this effect was shown to be mediated by a 50-fold increase of the expression of IL-22, 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, including 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 changes[1].

Prof. Dr. Severine Vermeire, M.D., Head of the IBD center at the University Hospitals Leuven, Belgium and Principal Investigator of the study, said: *"reaching our recruitment goal of 30 patients marks an important step as there is a strong need to develop additional drugs in this indication; too many patients still do not respond or stop responding to current treatments. We are looking forward to the top-line data from this study and also to transferring as many patients as possible onto the one year open-label extension study with ABX464, which will provide us with very important long-term safety and efficacy data."*

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

[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