



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

July 19, 2018

- **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.