ABIVAX enrolls first ulcerative colitis patient in new ABX464 proof-of-concept clinical trial

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- **Phase 2a trial triggers expansion of ABX464 to inflammatory indications**
- **Regulatory authorizations received in Belgium, Hungary and France**
- **Long term protocol for open-label follow-up study planned**

PARIS, November 20, 2017 at 8:00 a.m. CET – ABIVAX (Euronext Paris: FR0012333284 – ABVX) today, announced the enrolment of the first patient in the ABX464-101 proof-of-concept study of its lead product candidate ABX464 in subjects suffering from moderate-to-severe active ulcerative colitis.

ABX464-101 is a Phase 2a proof-of-concept study aimed at evaluating the safety and efficacy of ABX464 50 mg given once daily versus placebo 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 18 centers in eight European countries: France, Belgium, Germany, Poland, Hungary, Czech Republic, Spain and Austria. Regulatory and ethics committee authorizations already have been obtained in Belgium, Hungary and France.

Professor Hartmut Ehrlich, M.D., CEO of ABIVAX, said: "*Exciting preclinical and in vitro human data showing ABX464's efficacy in infammatory bowel disease models led us to undertake this trial in patients with ulcerative colitis. For example, ABX464 raised IL-22 and miR124 levels in in vitro human immune cells by 50- and 10-fold, respectively, indicating that ABX464 has powerful anti-inflammatory properties and is potentially synergistic with some of the established therapies for ulcerative colitis.*"

Thirty subjects will be enrolled and treated for eight weeks. The primary objective is to evaluate safety and tolerability of ABX464 in this indication. Several efficacy objectives including clinical and biologic remission and mucosal healing also are included in this study. A follow-up protocol was recently submitted allowing participating patients to be enrolled in a 12-month open label follow-up study.

The first patient was enrolled this week at the University Hospitals Leuven, Belgium.Top-line data are expected to be reported in the second half of 2018.

Dr Jean-Marc Steens, M.D., Chief Medical Officer at ABIVAX, commented: *"Launching this trial marks the start of a clinical research and development program that has the potential to positively impact the treatment options for patients suffering from IBD. The opportunity to study ABX464 in IBD inflammation came from clinical and preclinical anti-inflammatory effects observed in our research on this drug-candidate for treatment of HIV infection, where the HIV reservoir is the source of chronic inflammation."*

Prof Séverine Vermeire, Department of Gastroenterolog - University Hospitals Leuven, Departmental Chair Clinical & Experimental Medicine KU Leuven, Belgium and principal investigator of the study, commented: *"We welcome the involvement of ABIVAX in this therapeutic area that still carries a tremendous unmet medical need. Well designed studies, looking at objective endpoints, such as study ABX464-101, are critical in order to identify new drugs that can further improve treatment options for our patients."*