



ABIVAX receives French regulatory Approval to Begin Clinical Trial of ABX464 in Ulcerative Colitis

September 20, 2017

Initiating Phase 2a study in fourth quarter of 2017

Paris, September 20th, 2017 at 8 a.m. CEST – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases using its unique antiviral technology platform, today announced that the French National Regulatory Authority (ANSM) has approved the ABX464-101 Phase 2a “Proof-of-Concept” study of its lead product candidate ABX464 in patients with moderate to severe active ulcerative colitis

Professor Hartmut J. Ehrlich, M.D., CEO of ABIVAX, said: *“Preclinical data published in Nature Scientific Reports [1] show ABX464 dampened intestinal inflammation by triggering IL-22 production. As a result, we believe there is significant potential for the compound to be effective in patients with inflammatory bowel diseases (IBD). We are looking forward to initiating this study in the fourth quarter of 2017 and expect top-line data in the second half of 2018.”*

ABX464-101 is a Phase 2a study aimed at evaluating the safety and efficacy of ABX464 in 30 patients with ulcerative colitis who have failed or are intolerant to immunomodulators, anti-TNF α , vedolizumab and/or corticosteroids. Patients will be randomized to receive either ABX464 50mg or placebo given once daily for eight weeks. Exploratory objectives include assessing the clinical remission and mucosal healing of the ulcerative colitis lesions. This clinical study will be conducted in seven European countries: France, Belgium, Germany, Poland, Hungary, Czech Republic and Spain. Regulatory and ethics committee approvals are being sought in all these countries.

Professor Severine Vermeire, M.D., Department of Gastroenterology - University Hospitals Leuven, Departmental Chair Chronic Diseases, Metabolism & Ageing, KU Leuven, Belgium and principal investigator of the study commented: *“We are looking forward to the start of this study, as ulcerative colitis still carries a large unmet medical need. Clinical research with new drug candidates is greatly needed to further improve treatments.”*

Jean-Marc Steens, M.D., chief medical officer of ABIVAX added: *“This first clinical study with ABX464 in ulcerative colitis is a critical step to demonstrate the clinical relevance of the anti-inflammatory properties of ABX464. This demonstration may have clinical implications not only for patients with IBD, but also for patients with HIV who typically suffer from complications related to inflammation around the viral reservoirs.”*

[1] Please find the Nature Scientific Reports article using the following link: <https://www.nature.com/articles/s41598-017-04071-3>