ABIVAX to Initiate Long-Term Extension Study of ABX464 in Patients with Ulcerative Colitis

January 4, 2018

- **Protocol Authorized by Belgian Authorities, Ethics Committee**
- **Ulcerative colitis patients responding to ABX464 to be recruited into 12-month extension study**
- **Approval based on safety observed in long-term preclinical studies**

PARIS, Jan. 4, 2018, 8 a.m. CET – ABIVAX (Euronext Paris: FR0012333284 – ABVX), a biotechnology company harnessing the immune system to develop a functional cure for HIV and treatments for inflammatory/autoimmune diseases and cancer, today announced that the follow-up protocol ABX464-102 has been authorized by the Regulatory Authority and Ethics Committee in Belgium. The new study will recruit patients from the ongoing ulcerative colitis proof-of-concept study (ABX464-101) who are responding to treatment with ABX464 into the 12-month open label follow-up study (ABX464-102).The authorization was based on the safety of ABX464 observed in long-term preclinical studies.

"We are very pleased with this first authorization for a one-year treatment with ABX464, as it validates the encouraging safety profile of our compound, and we are looking forward to receiving the approvals from additional countries in the coming weeks and months" said **Professor Hartmut Ehrlich, M.D., CEO of ABIVAX**

ABX464-101 is an ongoing 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 18 centers in eight European countries. Full regulatory and ethics committee authorizations already have been obtained in Belgium, France, Hungary, Poland, Czech Republic, Spain and Germany.

ABX464-102 is a twelve-month open label follow-up study for patients with ulcerative colitis benefiting from the administration of ABX464 in the ABX464-101 study.

Professor Ian McGowan, M.D., Division of Gastroenterology, Hepatology and Nutrition at the University of Pittsburgh School of Medicine, added: *"The approval of the long-term protocol marks another important step in the clinical development of ABX464. Given the high unmet medical need in ulcerative colitis, we welcome the approval of the long-term follow-up study, allowing patients who are suffering from this devastating disease and are responding to treatment with ABX464 to continue receiving this new treatment for another 12 months."*