

## Abivax Chosen to Deliver ABX464 Oral Presentation at Digestive Disease Week (DDW) Conference in the U.S.

***New 9-month interim data from phase 2a ulcerative colitis open-label maintenance study  
Oral presentation to be given by Prof. Severine Vermeire, past President of the European Crohn's and Colitis Organisation (ECCO)***

**PARIS, March 5, 2019, 7:00 a.m. CET** – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biopharmaceutical company harnessing the immune system to develop novel treatments for patients with inflammatory/autoimmune, and viral diseases and cancer, announced that it has been selected after peer-review to deliver an oral presentation at the annual Digestive Disease Week (DDW) conference on data from ABX464-101, a phase 2a clinical trial of ABX464 to treat ulcerative colitis as well as 9-month interim data from the ongoing 12-month open-label “maintenance” extension study, ABX464-102. DDW, the world’s leading educational forum in gastroenterology, hepatology, GI endoscopy and gastrointestinal surgery, will be held at the San Diego Convention Center from May 18 - 21, 2019.

The Principal Investigator of the study, **Prof. Séverine Vermeire, M.D., Ph.D.**, Department of Gastroenterology - University Hospitals Leuven, Departmental Chair Clinical & Experimental Medicine KU Leuven, Belgium will present the data.

**Prof. Vermeire** commented: *“To have these data selected for the second time by peer reviewers for an oral presentation to an international audience of experts in the field is very exciting, and validates the potential role of this oral, investigational agent with a novel mechanism of action in ulcerative colitis and other inflammatory indications, a therapeutic area with a very large unmet medical need.”*

**Prof. William Sandborn, M.D.**, Director of the Inflammatory Bowel Disease (IBD) Center at University of California (UC) San Diego Health, and Chief, Division of Gastroenterology at UC San Diego School of Medicine, added: *“Although this was the first proof-of-concept phase 2a clinical trial with ABX464 in ulcerative colitis, the data from this randomized, placebo-controlled trial are quite encouraging and warrant further development of this first-in-class oral drug candidate in phase 2b. I am looking forward to collaborating with Abivax in bringing ABX464 into clinical trials in the United States.”*

ABX464-101 was conducted with 32 patients for induction treatment of moderate-to-severe ulcerative colitis (UC), refractory to immunomodulators, anti-TNF monoclonal antibodies, vedolizumab and/or corticosteroids. The final data from this 8-weeks randomized, double-blind, oral, placebo-controlled clinical study indicated that ABX464 was safe, well-tolerated, and demonstrated statistically significant efficacy based on both clinical and endoscopic endpoints in this study. The difference between ABX464 and placebo in mucosal healing was statistically significant ( $p=0.03$ ). Furthermore, the onset of the therapeutic effect of ABX464 was rapid, with a reduction of the Partial Mayo Score<sup>1</sup> between ABX464 and placebo being observed at the first assessment following treatment for two weeks, which became significant at eight weeks ( $p=0.02$ ; likelihood ratio CHI-square test).

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1. The Partial Mayo Score is composed of stool frequency, rectal bleedings and the physician’s global assessment of disease severity.



Similarly, the difference of the reduction of the Total Mayo Score<sup>2</sup> after eight weeks was statistically significant (p=0.03).

At the end of the completed 8-weeks induction treatment study, 22 UC patients (15 previously treated with ABX464 and 7 who had received placebo) opted to enroll in the 12-month open-label maintenance study, ABX464-102, with ABX464. Based on the long-term results of the study, the Data Safety Monitoring Board granted a positive opinion regarding a second extension for an additional 12 months, expanding ABX464-102 into a 24-month maintenance study. The protocol amendment has received regulatory and ethics approval in Belgium and Hungary, and the first patient started in this second year extension on January 24, 2019. Approval is expected soon in Poland.

*“We are thrilled to have the opportunity to deliver these impressive data, observed in clinical trials for our lead candidate, ABX464, which has broad potential for the treatment of inflammatory indications,”* said **Prof. Hartmut Ehrlich, M.D., Chief Executive Officer of Abivax.** *“ABX464 is a novel, potent oral anti-inflammatory agent, with a mechanism of action that has broad applicability and could potentially represent a paradigm shift in the treatment of ulcerative colitis as well as other inflammatory diseases. Currently marketed drugs for inflammation provide durable responses in only a fraction of patients and inflammation represents over a \$70 billion market opportunity.”*

Data from the ABX464-101 and ABX464-102 studies also were accepted for oral presentation at the 14<sup>th</sup> Congress of the European Crohn’s and Colitis Organisation (ECCO) – Inflammatory Bowel Diseases 2019, which will take place in Copenhagen, Denmark from March 6-9, 2019. **Dr Jean-Marc Steens, M.D., Chief Medical Officer at Abivax** will be presenting during ECCO a summary of the final data of its completed randomized, placebo-controlled phase 2a induction trial, ABX464-101, as well as 6 months interim data (at DDW: 9 months interim data) from its ongoing 12-month open-label “maintenance” extension study, ABX464-102.

## SESSION DETAILS

**Session Type:** Research Forum

**Session Title:** IBD Clinical Trials: Emerging Therapies

**Session Date & Time:** May 21, 2019 from 10:00 AM to 11:30 AM

**Presentation Title:** ABX464 IS SAFE AND EFFICACIOUS IN PROOF OF CONCEPT STUDY IN ULCERATIVE COLITIS PATIENTS

**Presentation Time:** 11:00 AM to 11:15 AM

ABX464 has a newly-elucidated mechanism of action. This was recently published in *Nature Scientific Reports* (**Weblink:** [www.nature.com/articles/s41598-018-37813-y](http://www.nature.com/articles/s41598-018-37813-y)) and confirms that ABX464 reduces inflammation by upregulating the selective splicing of a long non-coding RNA, thereby releasing high concentrations of splicing product miR-124, a novel, potent anti-inflammatory microRNA.

Based on the very encouraging data from study ABX464-101, Abivax already submitted the clinical trial applications (CTAs) of the phase 2b clinical study in 232 UC patients in the first countries, and CTA submissions of phase 2a proof-of-concept studies to treat Crohn’s disease and rheumatoid arthritis are scheduled for the next weeks.

## About Digestive Disease Week

Digestive Disease Week (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association

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<sup>2</sup> The Total Mayo Score is composed of stool frequency, rectal bleedings, endoscopic assessment and the physician’s global assessment of disease severity.



(AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18-21, 2019, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at [www.ddw.org](http://www.ddw.org)

### **About Abivax ([www.abivax.com](http://www.abivax.com))**

Abivax is mobilizing the body's natural immune machinery to treat patients with inflammatory/autoimmune diseases, viral diseases and cancer. A clinical-stage company, Abivax leverages its anti-inflammatory/antiviral and immune enhancing platforms to optimize candidates to treat inflammatory diseases, HIV and liver cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at [www.abivax.com/en](http://www.abivax.com/en).

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