

## Abivax's phase 2a ulcerative colitis clinical trial data selected for oral plenary presentation at 14<sup>th</sup> Congress of European Crohn's and Colitis Organisation

*Favorable safety and statistically significant efficacy of oral ABX464 demonstrated in a completed randomized, double-blind, placebo-controlled induction trial based on clinical and endoscopic endpoints*

*Six-months interim data from ongoing one-year open-label extension study (maintenance treatment) to be presented as well*

**PARIS, December 20, 2018, 7:00 a.m. CET** – Abivax (Euronext Paris: FR0012333284 – ABVX), a biotechnology company harnessing the immune system to develop treatments for inflammatory/autoimmune diseases, infectious diseases and cancer, today announced that its abstract has been accepted for oral presentation at the 14<sup>th</sup> Congress of the European Crohn's and Colitis Organization (ECCO) – Inflammatory Bowel Diseases 2019, which will take place in Copenhagen, Denmark from March 6-9, 2019. Abivax will be presenting a summary of the final data of its completed randomized, placebo-controlled phase 2a induction trial, ABX464-101, as well as interim data from its ongoing 12-month open-label "maintenance" extension study, ABX464-102.

### **Presentation details:**

**Title:** ABX464 is safe and efficacious in a proof of concept study in ulcerative colitis patients  
**Session #:** 8: IBD Horizons  
**Location:** Bella Center, Plenary Hall  
**Date:** March 8, 2019  
**Time:** 3:55-4:05 p.m.

*"We are very pleased that our abstract has been selected as a plenary presentation by ECCO's scientific program committee," said **Jean-Marc Steens, Chief Medical Officer** of Abivax. "This is a great scientific validation of the importance of these data and we are eager to share these promising results with the medical community, including many key IBD specialists who may be interested to participate in our upcoming phase 2b clinical trial."*

ABX464-101 was conducted with 32 patients for induction treatment of moderate-to-severe ulcerative colitis (UC), refractory to anti-TNF monoclonal antibodies or corticosteroids. The final data from this 2-month, double-blind, placebo-controlled clinical study indicated that ABX464 was safe, well-tolerated, and demonstrated statistically significant efficacy based on both clinical and endoscopic endpoints. The difference between ABX464 and placebo in colorectal mucosal healing was statistically significant ( $p < 0.03$ ). Furthermore, the onset of the therapeutic effect of ABX464 was rapid, with a difference in the reduction of the partial Mayo score<sup>1</sup> between ABX464 and placebo being

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<sup>1</sup> The partial Mayo Score is composed of stool frequency, rectal bleedings and the physician's global assessment of disease severity.



observed at the first assessment following treatment for two weeks, which became significant ( $p < 0.02$ ) at eight weeks (likelihood ratio CHI-square test). Similarly, the difference of the reduction of the total Mayo score<sup>2</sup> after eight weeks was statistically significant ( $p < 0.03$ )<sup>3</sup>.

At the end of the completed 2-month induction treatment study, 22 Patients (15 previously treated with ABX464 and 7 on placebo) were transferred to the 12-month open-label maintenance study with ABX464. A 6-month interim analysis of the maintenance study will be part of the ECCO presentation.

*“Patients with this devastating disease are in urgent need of innovative treatments, as too many of them do not respond or stop responding to current drugs,”* said **Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax**. *“We are dedicated to advancing the clinical development of ABX464 in ulcerative colitis as well as in other inflammatory diseases including Crohn’s disease and rheumatoid arthritis. The completed clinical protocol for our phase 2b dose-ranging study in 232 patients with moderate-to-severe ulcerative colitis will be submitted to regulatory authorities in January 2019, followed by two phase 2a clinical trial submissions in rheumatoid arthritis and Crohn’s disease.”*

#### About Ulcerative Colitis

Ulcerative colitis is a debilitating inflammatory bowel disease in adults and children, with limited therapeutic management options for many patients. It is estimated that close to 1 million patients with ulcerative colitis live in the United States, 650,000 in the EU and >2.7 million globally<sup>4</sup>. Pharmaceutical sales for this disease in the major global markets are estimated to be around \$5.5 billion in 2017. For IBD (inflammatory bowel disease), which includes both ulcerative colitis and Crohn’s disease, the sales in the major global markets are estimated to be around \$15 billion for the same period. The financial potential of treatments in the anti-inflammatory space are exemplified by anti-TNF monoclonal antibodies (Humira, Remicade, Simponi) with estimated global annual sales of > \$30 billion, including at least \$2.5 billion for ulcerative colitis.

#### About ABX464

Inflammation is a cornerstone of inflammatory bowel disease (IBD), more specifically in ulcerative colitis and Crohn’s disease. When evaluated in a mouse model of IBD, ABX464 demonstrated a long-lasting effect in preventing the typical symptoms of inflammatory colitis, including histological improvements<sup>5</sup>. A ten-fold increase of miR124, a micro-RNA with potent anti-inflammatory properties in peripheral blood mononuclear cells (PBMCs) was observed. ABX464 was shown to target the cap binding complex (CBC), which is a novel mechanism of action for anti-inflammatory drugs. By ABX464 binding to the CBC, it reinforces the biological functions of this complex in cellular RNA biogenesis including splicing. Therefore, the molecule acts inside injured immune cells to preserve the integrity of newly synthesized RNA. ABX464 enhanced the expression and splicing of a single long non-coding RNA to generate the anti-inflammatory miR-124. This work was conducted by the cooperative laboratory between Abivax and the CNRS (Centre National de Recherche Scientifique) in Montpellier, France, headed by Prof. Jamal Tazi.

#### 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). Follow us on Twitter @ABIVAX\_

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<sup>2</sup> The total Mayo score is composed of the 3 parameters listed above, plus mucosal appearance at endoscopy

<sup>3</sup> [See press release dated September 4, 2018](#)

<sup>4</sup> Company estimate based on Global Data

<sup>5</sup> K Chebli et al., The Anti-HIV Candidate ABX464 Dampens Intestinal Inflammation by Triggering IL-22 Production in Activated Macrophages. Nature Scientific Reports 2017, DOI:10.1038/s41598-017-04071-3



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