

Abivax Presents Impressive New Phase 2a ABX464 Ulcerative Colitis 6-Months Maintenance Study Data in Oral Plenary Session at Annual Congress of European Crohn's and Colitis Organisation (ECCO)

***Magnitude and durability of efficacy further increased with oral ABX464 50mg once-daily
maintenance treatment***

***Maintenance therapy further increased benefits on partial Mayo Score and fecal
calprotectin biomarker***

Long-term safety continues to be very good in maintenance study

Mean treatment time now is exceeding 10 months for study patients

First clinical trial applications for Phase 2b trial in ulcerative colitis submitted

Preparing Phase 2a studies in rheumatoid arthritis and Crohn's disease

PARIS, March 11, 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 diseases, viral diseases and cancer, delivered an oral plenary presentation at the 14th Congress of European Crohn's and Colitis Organisation (ECCO) in Copenhagen, Denmark on March 8, 2019. The presentation, given by **Dr. Jean-Marc Steens, M.D., Chief Medical Officer of Abivax**, showed that the magnitude of ABX464's effects continued to increase during the first six months of the ongoing 12-month open-label, roll-over "maintenance" extension study, ABX464-102. This maintenance study was initiated upon completion of ABX464-101, a phase 2a induction placebo-controlled study of ABX464 for the treatment of patients with moderate to severe ulcerative colitis (UC).

Dr. Steens commented: *"Ulcerative colitis is a debilitating chronic disease that is currently severely under addressed by marketed drugs like biological anti-TNF and steroid therapeutics. The impressive results from the induction phase, coupled with the increasing magnitude and durability of effect shown in the maintenance study, suggest oral once-daily ABX464 could represent a substantial improvement to available treatment options for patients suffering from ulcerative colitis. Furthermore, the differentiated mechanism of ABX464 may well be complementary to existing anti-TNF and steroid therapies. These data have also convinced the study's DSMB to recommend an additional 12-month extension to the study, increasing the total maintenance to 24 months."*

Abivax will also be hosting a webcast to discuss these data as well as 2018 financial results on Thursday, March 14. The live and recorded webcast can be accessed via the following link: <https://edge.media-server.com/m6/p/neva9py8>. Audio of this webcast can also be accessed via international dial-in, included at the end of this release.

Prof. Séverine Vermeire, M.D., Ph.D., Department of Gastroenterology - University Hospitals Leuven, Belgium, past President of ECCO and Principal Investigator of the study commented: *"We are extremely encouraged by the ABX464 6-month maintenance study data. These interim results and ABX464 novel mode of action further support the potentially important role of this oral drug to treat a*



disease for which there continues to be a broad unmet medical need. We look forward to developing this drug candidate further in the ongoing extension study as well as in the upcoming Phase 2b study, for which clinical trial applications have already been submitted in the first countries.”

At the end of the completed 2-month induction study in 32 patients, 22 of these (15 previously treated with ABX464 and 7 who had received placebo) opted to enroll in the 12-month open-label maintenance study, ABX464-102. At month six, 19 of the 22 patients were still in the study, receiving a once-daily, oral capsule of 50mg ABX464. The 6-month interim analysis showed that ABX464 continued to have a good safety profile when administered chronically.

The efficacy data as assessed by partial Mayo Score (pMS)¹ show that 12 of 13 patients (92%) who were originally in the active group during the induction phase are still improving during the maintenance study with an overall mean reduction of 76% versus baseline during their total of 8 months treatment with ABX464, including a 36% decrease of pMS during the maintenance phase. The 6 patients who entered the maintenance study after placebo during the 2 months induction phase saw a mean decrease of 68% in pMS during their 6 months of treatment with ABX464.

Importantly, the reduction in pMS was correlated with a major reduction of fecal calprotectin, the most widely used biomarker in UC. During the maintenance study at month 6, fecal calprotectin was reduced by an overall of 98% versus baseline in patients on ABX464 during induction (68% after 2 months induction and 30% during maintenance), and by 91% in former placebo patients. Importantly, the mean fecal calprotectin levels in the 2 groups decreased to 86 and 54 ug/g respectively, and thus very close to normal values, which are in the range of up to 50 ug/g for individuals with no IBD, between 50 and 200 ug/g for borderline cases, and above 200 ug/g for patients with IBD.

In the Phase 2a ABX464-101 study, ABX464 induction treatment was conducted in 32 patients with moderate-to-severe UC, refractory to anti-TNF monoclonal antibodies or corticosteroids. The final data from this 2-month double-blind placebo controlled clinical study indicated that oral, once-daily 50mg ABX464 was safe, well-tolerated, and demonstrated statistically significant efficacy based on both clinical and endoscopic endpoints in this study. The proportion of subjects achieving clinical remission was greater in the ABX464 group than in the placebo group (35.0% vs. 11.1%, p=ns). The difference between ABX464 and placebo treated patients in colorectal mucosal healing was statistically significant (50% vs. 11%, p=0.034). Furthermore, the onset of the therapeutic effect of ABX464 was rapid, with a reduction of the pMS between ABX464 and placebo being observed at the first assessment following treatment for two weeks, which became significant at eight weeks (-3.9 vs. -1.8, p=0.029; likelihood ratio CHI-square test). Similarly, the difference of the reduction of the total Mayo Score (tMS)² after eight weeks was statistically significant (-4.6 vs. -2.1, p=0.029). For additional details on the induction study results, please refer to a previous press release:

<https://abivax.gcs-web.com/static-files/92ad8dc5-11c9-44ff-8fbc-bdc337035650>

“Given the increasing efficacy and continued safety of ABX464 during the maintenance study, these data are a big step forward in the development of this exciting molecule.” said **Prof. Hartmut J. Ehrlich, MD, Chief Executive Officer at Abivax**, and he continued *“Moreover, our research suggests that ABX464’s observed anti-inflammatory effects may also extend into other inflammatory diseases with high unmet medical need, like Crohn’s disease and rheumatoid arthritis, the clinical investigation of which will be initiated shortly. In addition, ABX464 is in proof-of-concept pre-clinical models for psoriasis, multiple sclerosis and Parkinson’s disease which, if positive, will pave the way into additional clinical trials as well.”*

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

² The total Mayo Score is composed of the 3 parametrs listed above, plus mucosal appearance at endoscopy



ABX464 has a newly-elucidated anti-inflammatory mechanism of action. This was recently published in *Nature Scientific Reports* (**Weblink:** www.nature.com/articles/s41598-018-37813-y) and confirms that ABX464 dampens inflammation by upregulating the selective splicing of a long non-coding mRNA, the splicing products, which include high concentrations of miR-124, a natural, endogenous microRNA with potent anti-inflammatory properties.

Based on the very encouraging data from study ABX464-101, Abivax has already submitted clinical trial applications in the first countries (France, Canada, Italy and Slovakia) to initiate a phase 2b clinical trial in 232 UC patients, and is preparing phase 2a proof-of-concept studies to treat Crohn's disease and rheumatoid arthritis patients.

About Ulcerative Colitis

Ulcerative colitis is a debilitating inflammatory bowel disease in adults and children, with limited therapeutic management options for many patients who are not responding to or losing their responsiveness to current therapies. 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 globally³. 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 ECCO

The European Crohn's and Colitis Organisation (ECCO), founded in 2001 to improve the care of patients with inflammatory bowel disease (IBD) in Europe, is now the largest forum for specialists in IBD in the world. It is a non-profit association, which successfully expanded from an organisation comprising 14 Country Members to an association assembling 36 member states of the Council of Europe and facilitating collaborations beyond Europe's borders. In 2009, ECCO introduced individual membership allowing anyone around the globe interested in IBD to both benefit from its programmes and services and to join us ECCO's mission.

About Abivax (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. Follow us on Twitter @ABIVAX_

WEBCAST PRESENTATION

Abivax senior management will host a webcast and teleconference Thursday, March 14 at 2:00 pm CET (Paris time) / 9am ET (NYC time), to discuss these clinical results, 2018 financial results, and address questions.

Attendees can participate by weblink (<https://edge.media-server.com/m6/p/neva9py8>) or connect by phone using the following coordinates:

³ Company estimate based on Global Data



Telephone conference

Dial in details, Participants:

Confirmation Code: **8987717**

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Belgium, Brussels+32 (0) 1039 1206
China8008709889
France.....0805101655
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