Press Release

Abivax receives DSMB recommendation to continue ongoing extension study of its completed phase 2a clinical trial in ulcerative colitis patients

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

One-year open-label extension study ongoing, with patients already well treated with ABX464 for a total of 5 to 12 months (induction and maintenance study)

Abivax is submitting a protocol amendment to authorities to allow for a total of 2 years of treatment, following up on such requests from the clinical investigators and a positive recommendation by the Data Safety Monitoring Board

Protocol for phase 2b clinical trial in 250 patients to be submitted in January 2019 for regulatory and ethics committee approvals.

PARIS, December 6, 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 the Data Safety Monitoring Board (DSMB) has recommended continuation of its ongoing 12-month open-label "maintenance" extension study, ABX464-102, continuing its completed randomized, placebo-controlled Phase 2a induction trial, ABX464-101.

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 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 colorectal mucosal healing was statistically significant ($p<0.03$). Furthermore, the onset of the therapeutic effect of ABX464 was rapid, with a difference of the reduction of the partial Mayo score[1] between ABX464 and placebo being 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[2] after eight weeks was statistically significant ($p<0.03$)[3].

Based on the long-term results of ABX464 (5 to 12 months of treatment already completed in induction and/or maintenance studies), the study's Data Safety and Monitoring Board recommended continuation of the maintenance study and, in addition, granted a positive opinion regarding a second extension for an additional 12 months, making ABX464-102 into a 24-month extension study. The protocol amendment is being submitted to regulatory authorities this week.

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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.
[2] The total Mayo score is composed of the 3 parameters listed above, plus mucosal appearance at endoscopy
[3] See the Press Release

"We are very pleased, as the extension of the ABX464-102 maintenance study from 12 to 24 months was proposed by the investigators based on medical benefit and was initially requested by trial patients, suffering from this chronic disease, who wanted to ensure continued access to ABX464 treatment," said **Jean-Marc Steens, M.D.,** Chief Medical Officer of Abivax.

"I strongly support the recommendation of the Data Safety Monitoring Board to not only continue the current one year maintenance study, but also to extend the study for a second year, which we expect can be very beneficial for the patients currently receiving ABX464," said **Prof. Severine Vermeire, M.D**., Head of the IBD center at the University Hospitals Leuven, Belgium, former President of the European Crohn's and Colitis Organization and Principal Investigator of the study. She added: "*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. We fully support Abivax in its efforts to further develop this promising compound both in ulcerative colitis as well as in other inflammatory diseases including Crohn's disease. As the principal investigator I look forward to the initiation of the phase 2b dose-ranging study of ABX464 in ulcerative colitis."*

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 months open-label maintenance study with ABX464. As of today, 20/22 patients have completed at least 5 months of treatment in the maintenance study, with one patient being treated with ABX464 for more than one year.

"The favorable safety and medical benefit observed in this study further strengthen our commitment to bring ABX464 to the many patients with ulcerative colitis and other inflammatory diseases, like Crohn's disease and rheumatoid arthritis, who are not adequately helped by current therapies," said **Prof. Dr. Hartmut J. Ehrlich, M.D**., CEO of Abivax. "*We will submit the already completed protocol of our previously announced phase 2b dose-ranging study in 250 patients with moderate to severe ulcerative colitis to regulatory authorities in January 2019, followed by phase 2a clinical trial submissions in rheumatoid arthritis and Crohn's disease during Q1 of 2019."*

The full clinical trial data of the completed induction study and interim data of the maintenance study will be presented at upcoming international scientific conferences, as well as submitted for publication in a leading medical journal.

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[4]. 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[5]. A ten-fold

[4] Company estimate based on Global Data

[5] 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

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)

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 antiinflammatory/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_

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