Press Release

Abivax Delivered Oral Presentation at Leading US International Gastroenterology Conference on ABX464 Phase 2a Nine-month Maintenance Data Demonstrating Long Term Efficacy and Safety in Ulcerative Colitis

Lecture presentation at Digestive Disease Week in San Diego, California on May 21, 2019

At nine months treatment with ABX464, 18 of 19 patients have sustained clinical responses

Median level of biomarker fecal calprotectin sharply decreased to normal values, indicative of mucosal healing

All patients in the maintenance phase at six months remain in study at nine months, supporting durability of safety and efficacy

Patients now on daily treatment for an average of 14 months, with the longest patient being treated for 18 months

PARIS, May 22, 2019, 8:00 a.m. (CEST) – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop treatments for inflammatory diseases, viral diseases, and cancer, yesterday presented nine-month interim data from ABX464-102, the one year open-label maintenance study in patients with moderate to severe ulcerative colitis (UC), at the annual Digestive Disease Week (DDW) conference in San Diego, CA, USA.

Prof. Dr. Severine Vermeire, M.D., Ph.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, said: *"The ABX464-102 study continues to provide evidence of a robust and consistent efficacy signal in ulcerative colitis patients undergoing ABX464 treatment across all clinical endpoints, and also according to evaluated biomarkers such as fecal calprotectin levels. These six and now nine-months interim results from the maintenance study are very promising and we fully endorse the further development of this exciting new oral compound, both in ulcerative colitis as well as in other inflammatory diseases."*

Prof. Dr. 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, said: *"Only two-thirds of patients respond to currently available treatments, including biologics, and half of the responders stop responding after six to twelve months, so there is a large unmet need for effective ulcerative colitis therapies. This is a debilitating disease that greatly affects patients' quality of life and requires expensive and cumbersome therapies. The innovative mechanism of action of ABX464 and data from this trial represent a promising new potential approach to the treatment of ulcerative colitis that could deliver these patients an easily administered, oral, long-term therapeutic management option."*

ABX464-101 induction study results demonstrated rapid onset of efficacy and improvement in clinical remission rate

The Phase 2a induction study ABX464-101 was a randomized, double-blind, placebo-controlled Phase 2a induction study evaluating the safety and efficacy of ABX464 50 mg given orally, once-daily for two months in subjects with moderate-to-severe active ulcerative colitis who have failed immunomodulators, anti-TNFα, vedolizumab and/or corticosteroids. The study was conducted at 15 centers in six European countries. Twenty-nine of the 32 recruited patients, randomized 2:1 to receive ABX464 as a once daily, oral tablet or placebo, completed the study per protocol.

The results of this study were reported in September 2018 and showed a rapid onset of efficacy within 2 weeks after initiation of treatment. At the end of the 8 weeks induction treatment, clinical remission was observed in 35% of the ABX464 treated patients (placebo: 11%) and mucosal healing in 50% (placebo: 11%, p = 0.03) (link to Abivax press release from September 4, 2018).

In four countries (Belgium, Poland, Hungary and Czech Republic), patients who completed the ABX464-101 study had the option to roll over into a 12-Month open-label extension study, ABX464-102, in which 22 patients were enrolled. Six-Month interim data from ABX464-102 presented at the ECCO (European Crohn's and Colitis Organisation) annual conference in March 2019 showed that 19 of 22 patients were still on study, and similar to the induction study ABX464-101, ABX464 was safe and well tolerated. Partial Mayo Score continued to decrease and fecal calprotectin levels went down to values approaching normal levels (link to Abivax press release from March 11, 2019).

Nine-month ABX464-102 maintenance study results presented yesterday confirmed durability of safety and efficacy of ABX464

After nine months of open-label treatment with ABX464, all 19 patients remain in the study, for whom the interim data were presented yesterday at DDW. Of these 19 patients, 18 demonstrated a sustained clinical response:

- 7 patients (6 initially on ABX464, 1 initially on placebo) were in clinical remission at the end of the eight-week induction phase. After 2 months maintenance, post-induction, clinical remission was confirmed in all 7 patients and they all continued to have at least a clinical response at month 9 (clinical remission not assessed due to the lack of endoscopy). Endoscopy for the assessment of remission status is planned at month 12.
- 12 patients (7 initially on ABX464, 5 initially on placebo) were not in clinical remission at the end of the eight-week induction phase but 6 of them had clinical response at that time point. After 2 months maintenance, 6 patients had endoscopic improvement. At Month 9, 11 patients showed at least a clinical response. Endoscopy is planned at Month 12.

Levels of fecal calprotectin, the biological marker for Inflammatory Bowel Disease (IBD), sharply decreased from a median of 1044µg/g at baseline of the induction study to 24µg/g at nine months of the maintenance study, reaching normal levels in healthy individuals (<50µg/g), which is indicative of mucosal healing.

The initial 12 months maintenance study has now been approved by all concerned regulatory authorities and ethics committees to be extended for a second year.

Dr. Jean-Marc Steens, M.D., Chief Medical Officer of Abivax said: *"The results from the eight weeks induction study, reported in September 2018, exceeded our expectations given the statistically significant and robust efficacy observed in this phase 2a study in patients refractory to available therapies, including anti-TNF monoclonal antibodies. The safety and durability of the effect at this nine months interim analyses of the open label maintenance study further confirm our hypothesis that ABX464's novel mechanism of action would result in potent and durable anti-inflammatory responses in these patients. We look forward to developing and potentially marketing ABX464 as a well-tolerated oral treatment for this large patient population with high unmet medical need."*

About ABX464

ABX464 was shown to target the cap binding complex (CBC), which is a novel mechanism of action for anti-inflammatory drugs. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis including splicing. ABX464 enhances the expression and selective splicing of a single long non-coding RNA to generate the anti-inflammatory miR-124, which acts by downregulating proinflammatory cyto- and chemokines like TNF-α, Il-6 and MCP-1, thereby putting a brake on inflammation. A seven- to ten-fold increase of miR124 was observed in peripheral blood mononuclear cells (PBMCs), and in colorectal biopsies of UC patients treated with ABX464.

ABX464 in Ulcerative Colitis

The new Phase 2b trial (link to ClinicalTrials.gov) is a randomized, double-blind, placebo-controlled, dose-ranging study in 232 UC patients that will have four arms: three escalating doses of once-daily oral ABX464 (25 mg/day, 50 mg/day and 100 mg/day) and placebo. The study will be conducted in up to 150 study sites in more than 15 countries under the leadership of its steering committee (Prof. Severine Vermeire, M.D., Ph.D., Prof. Herbert Tilg, M.D. Ph.D., Prof. Xavier Hebuterne, M.D., Ph.D., and Prof. William Sandborn, M.D.), and includes an eight week induction phase followed by an open-label maintenance study with ABX464. The primary endpoint is reduction in modified Mayo Score at 8 weeks, and secondary endpoints will include clinical remission, endoscopic improvement and biomarker fecal calprotectin. Full regulatory and ethics approvals have already been granted in Canada, with first patient enrollment expected in Q2 of this year and top-level results expected around the end of 2020.

ABX464 in other Inflammatory Diseases

Based on mechanistic, pre-clinical and clinical data from studies with ABX464 suggesting its broad therapeutic applicability in inflammatory indications, Abivax is also preparing two additional international phase 2a clinical studies of ABX464 in rheumatoid arthritis and Crohn's disease, in 60 and 30 patients respectively. Study planning is well advanced for rheumatoid arthritis, with first patient enrollment scheduled in Q2, 2019 (link to ClinicalTrials.gov).

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. It is estimated that nearly 1 million patients with ulcerative colitis live in the US, 650,000 in Europe, and over 2.7 million patients globally, representing a potential market opportunity of up to $5.5 billion annually, based on 2017 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached $15 billion[1]. The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of $70 billion, a market and patient population that the Company believes could benefit from ABX464.

[1] Source: Gobal Data

CALENDAR OF UPCOMING EVENTS:

- October 19-23, 2019: Planned presentation of 12-months maintenance data with ABX464 in UC (including endoscopy) at the annual United European Gastroenterology (UEG) week in Barcelona, Spain

About ABIVAX (www.abivax.com)

ABIVAX is mobilizing the body's natural immune machinery to treat patients with viral infections, autoimmune diseases and cancer. A clinical-stage company, ABIVAX leverages its antiviral and immune enhancing platforms to optimize candidates to treat ulcerative colitis and other inflammatory diseases, viral diseases 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 LinkedIn and Twitter @ABIVAX_

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