Press Release

First patient enrolled in Abivax ABX464-103 Phase 2b Clinical Trial in Patients with Ulcerative Colitis

Trial with once a day oral dosing to be conducted in 232 patients with moderate to severe ulcerative colitis at more than 150 sites in over 15 countries

Published 9-month interim results of ongoing Phase 2a maintenance study ABX464-102 confirmed durability of safety and efficacy

ABX464-102 proceeding well, with 12-month treatment outcomes planned for presentation at UEG (United European Gastroenterology) Week (Oct. 19-23, 2019, Barcelona)

Ulcerative colitis is a severe, debilitating disease with 2.7 million diagnosed patients in G7 (US, G5 Europe & Japan) countries and pharmaceutical sales of $ 5.6 billion in 2018

PARIS, August 19, 2019, 6:00 p.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, announced today that the first patient was enrolled in its Phase 2b clinical trial of ABX464 with once a day convenient oral dosing for treatment of patients with moderate to severe active ulcerative colitis (UC).

In total, the clinical trial will be conducted in over 15 countries in Europe and in Canada. Nine countries involved have already approved the study.

Prof. Hartmut J. Ehrlich M.D., Chief Executive Officer of Abivax said: *"Given the safety as well as the magnitude and durability of the therapeutic effect observed with ABX464 in the proof of concept Phase 2a induction and maintenance studies in patients refractory to available therapies, including anti-TNF monoclonal antibodies, we are excited to initiate the next stage of clinical development with this promising drug candidate. The objectives of this Phase 2b study are to confirm that ABX464's novel mechanism of action will result in potent and durable anti-inflammatory responses in a much larger patient population, and to define the optimal dose for subsequent Phase 3 testing. We look forward to developing and potentially marketing ABX464 as a well-tolerated and highly efficacious oral treatment for the large population of ulcerative colitis patients who currently have only limited treatment options."*

The new Phase 2b trial ABX464-103 (link to ClinicalTrials.gov) is a randomized, double-blind, placebo-controlled, dose-ranging study in 232 UC patients that will have four arms: three with escalating doses of once-daily oral ABX464 (25 mg/day, 50 mg/day and 100 mg/day) and one placebo arm. The study will be conducted at up to 150 study sites in more than 15 countries under the leadership of its steering committee (Prof. Séverine Vermeire, M.D., Ph.D., University Hospitals Leuven, Belgium, Prof. Herbert Tilg, M.D. Ph.D., Medical University Innsbruck, Austria, Prof. Xavier Hebuterne, M.D., Ph.D., University Hospital Nice, France, and Prof. William Sandborn, M.D., University of California San Diego School of Medicine, USA) and includes a 16-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. Top-line data from the induction study are expected around the end of 2020.

Prof. Séverine 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: *"Besides very impressive efficacy results across all clinical and endoscopic endpoints, the proof of concept induction and maintenance Phase 2a studies also showed a reduction of the highly elevated biomarker fecal calprotectin to normal levels. With the ABX464-103 study, we are planning to confirm this effect in a statistically relevant number of patients and, at the same time, will evaluate different doses to define the optimal dose for subsequent Phase 3 testing. We are looking forward to including patients in this exciting program with ABX464, a novel, first-in-class molecule with an innovative mode of action that could make a difference in treating patients suffering from this emaciating inflammatory disease."*

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, said: *"In general, less than one-third of patients with moderate to severe ulcerative colitis achieve the ultimate treatment goal of being symptom-free ("clinical remission") with currently available treatments, including biologics. Moreover, despite continued treatment, about half of the patients initially in clinical remission lose their responsiveness to treatment after six to twelve months, so there is a large unmet need for new effective therapies. Ulcerative colitis is a debilitating disease that greatly affects patients' quality of life and requires expensive and cumbersome treatments. ABX464's innovative mechanism of action as well as the exciting Phase 2a data so far suggest a promising new approach to the treatment of ulcerative colitis that could provide an easy-to-administer, oral, long-term therapeutic management option for these patients."*

About ABX464

ABX464 was shown to exert its anti-inflammatory effects through a novel mechanism of action; it binds to the cap binding complex (CBC), which essentially sits at the 5' end of every RNA molecule in the cell. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis. Specifically, ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA, miR-124, which downregulates pro-inflammatory cytokines and chemokines like TNF-α, IL-6 and MCP-1, thereby putting a brake on inflammation and suggesting broad potential as a novel anti-inflammatory therapeutic agent. A seven- to ten-fold increase in miR124 levels was observed in peripheral blood mononuclear cells (PBMCs) from healthy volunteers upon exposure to ABX464 and also in colorectal biopsies of UC patients treated with ABX464. ABX464 does not impact the splicing of cellular genes.

ABX464 in Ulcerative Colitis

The ABX464-101 induction study showed a rapid onset of clinical improvements as well as efficacy in patients naïve or resistant to biologics

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. Patients with moderate to severe active ulcerative colitis who have failed immunomodulators, anti-TNF-α, vedolizumab and/or corticosteroids were given 50 mg of ABX464 orally, once-daily for two months. The study was conducted at 15 centers in six European countries. Of the 32 recruited patients, randomized 2:1 to receive ABX464 as a once-daily oral tablet or placebo, 29 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-week 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). The efficacy of ABX464 was similar in patients naïve or resistant to biologics (e.g. anti-TNF-α or Vedolizumab).

ABIVAX presented 9-month ABX464-102 maintenance study results that confirmed durability of safety and efficacy of ABX464

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. Nine-month interim data from ABX464-102 presented at the DDW (Digestive Disease Week) annual conference in May 2019 in San Diego showed that 19 of 22 patients were still on study, and similar to the induction study ABX464-101, ABX464 was safe and well tolerated. The Partial Mayo Score continued to decrease and fecal calprotectin levels went down to normal levels (link to Abivax press release from May 22, 2019). 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 a clinical response at month 9 (clinical remission was not assessed at this point of time). 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 a 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 1,044 µg/g at baseline of the induction study to 24 µg/g at nine months of the maintenance study, thus reaching normal levels in healthy individuals (< 50 µg/g), which is indicative of mucosal healing.

The initial 12-month maintenance study was approved by all concerned regulatory authorities and ethics committees to be extended for a second year.

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 initiated an additional international Phase 2a clinical study of ABX464 in 60 patients with rheumatoid arthritis (link to ClinicalTrials.gov) a few weeks ago (link to Abivax press release from August 1st, 2019). Furthermore, Abivax is planning the initiation of a clinical study in 30 patients with Crohn's disease (link to ClinicalTrials.gov) by the end of this or early next year.

Despite the success of marketed therapies, the inflammatory disease space represents an area of high unmet medical need and corresponding substantial market opportunities. It is estimated[1] that about 4,2 million patients are diagnosed with RA in the G7 (US, G5 Europe & Japan) countries and the pharmaceutical sales in this indication were $24.4 billion in 2018. At the same time, over 2.7 million people are diagnosed with ulcerative colitis globally, representing a potential market opportunity of up to $5.6 billion annually (G7), based on 2018 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached nearly $16 billion. 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: GlobalData

CALENDAR OF UPCOMING EVENTS:

- October 19-23, 2019: Planned presentation of 12-month maintenance data with ABX464 in UC (including endoscopy) at the annual United European Gastroenterology (UEG) Week in Barcelona, Spain. In addition, the Company plans to host a one-hour breakfast symposium on ABX464 during the conference.

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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