ABX464 shows excellent long-term efficacy data in Abivax's phase 2b maintenance trial in ulcerative colitis

October 18, 2021

Impressive clinical remission in 58.4% (ITT) of 101 patients after 48 weeks of once-daily oral 50mg ABX464, showing both maintained as well as further improved efficacy

Favorable safety and tolerability profile continues to support ABX464 chronic use potential

Launch of global phase 3 program with ABX464 in ulcerative colitis in preparation, with end-of-Phase-2 US FDA meeting in Q4 2021 and EMA Scientific Advice in early Q1 2022

Abivax's late-breaking abstract presentation and Live Industry Symposium at UEG Week Virtual 2021 now publicly available

PARIS, France, October 18, 2021 – 6:00 pm (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, today reports new results from an extended set of patients in its ongoing open-label maintenance study, following the phase 2b induction study of once-daily oral 50mg ABX464 to treat ulcerative colitis (UC). These new data from the ongoing maintenance trial (data cut-off September 15, 2021) were presented during the **late-breaking abstract presentation** at UEG Week Virtual 2021 on October 4 by principal investigator Prof. Séverine Vermeire and are summarized in this release. These data emphasize ABX464's capacity to maintain and further improve pat ient-outcomes over time, as well as its continued favorable safety and tolerability.

Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, and principal investigator of the study, said: *"Patients suffering from chronic inflammatory diseases, such as UC, often struggle to find a suitable treatment. Indeed, there is significant unmet medical need as a significant proportion of UC patients stop responding to currently available therapies within the first year of treatment, or do not respond at all. More than 80% of the patients in clinical remission at the end of induction were still in remission with a treatment of 50mg once daily oral ABX464 after the first year of maintenance treatment. In addition, almost 50% of the patients who were not in clinical remission after the induction study, achieved clinical remission during this first year of maintenance. ABX464 showed a persistent good safety and tolerability profile during the first year of treatment."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"We are very pleased with the confirmation of the long-term efficacy of ABX464 for the treatment of ulcerative colitis. This trend was already observed in the phase 2a proof-of-concept study, in which 50% of the patients (ITT) were still in clinical remission after 3 years of treatment. These impressive results are now further strengthened by the first 101 patients who completed the one-year maintenance in phase 2b. Importantly, most published maintenance studies with other drugs only allowed patients who already showed a clinical response in the short-term induction study to enter into maintenance, thereby overestimating their long-term efficacy rate. In contrast, all patients had the possibility to continue their treatment in the ABX464 maintenance study, irrespective if they had a clinical response or not at the end of induction, thereby giving a chance even to the most severe cases. We are committed to rapidly bringing ABX464 into phase 3 testing, as we want to make this potentially transformative drug-candidate available as quickly as possible to patients suffering from ulcerative colitis."*

ABX464 phase 2b clinical maintenance study in ulcerative colitis – 101 patients completed 48 weeks
The new data from the phase 2b open-label extension study in UC, presented by Prof. Séverine Vermeire during the late-breaking abstract session at UEG Week Virtual 2021, included 101 patients who completed 48 weeks of chronic treatment with ABX464 as of September 15, 2021.

97.7% (217/222) of all patients who completed the phase 2b induction study, irrespective of treatments or treatment outcome during the induction phase, enrolled in the subsequent open-label maintenance study to evaluate the long-term safety and efficacy profile of ABX464 for up to two years.

	All patients		**Patients with clinical response[1] after induction**		**Patients without clinical response after induction**	
At week 48	PP[2] n=88	ITT[3] n=101	PP n=54	ITT n=63	PP n=34	ITT n=38

Clinical remission[4], *	n=59 (67%)	n=59 (58.4%)	n=40 (74%)	n=40 (63.5%)	n=19 (55.9%)	n=19 (50%)

* Drop-outs (13 patients) were considered as treatment failures in the ITT analysis.

Among the subset of 101 patients for whom 1 year maintenance data is currently available (cut-off date: September 15, 2021), 28 had entered the maintenance study already in clinical remission: 23/28 (82.1%) of these patients stayed in clinical remission and only 5/28 patients (17.9%) lost clinical remission during this first year of maintenance.

Importantly, 36/73 patients (49.3%) who were not in clinical remission at the end of induction achieved a *de novo* clinical remission during the first year of maintenance.

Remarkably, the clinical remission rate for patients who did not show at least a clinical response at the end of the induction phase was 55.9% (PP) and 50% (ITT) after 48 weeks of treatment, demonstrating that long-term administration of ABX464 provided substantial clinical benefits also for these patients.

During the induction and the maintenance phases of the phase 2b study, ABX464 continued to show a good safety and tolerability profile, confirming the data already generated in over 850 patients and volunteers treated with ABX464 so far.

In May and September 2021, Abivax already announced the **top-line** and **full results**, respectively, of this randomized, placebo-controlled phase 2b trial of ABX464 in moderate to severe ulcerative colitis patients following induction treatment.

254 patients with moderate to severe active ulcerative colitis were enrolled in this phase 2b trial and randomized to three once-daily oral ABX464 treatment groups (25mg, 50mg and 100mg) or placebo. 50% of these patients had inadequate response, loss of response, or intolerance to biologics and/or JAK inhibitors treatments while the other 50% were refractory to conventional treatments. Endoscopies were read centrally and in a blinded fashion by independent reviewers. The baseline disease characteristics were well balanced across all ABX464 dose groups and the placebo group. Enrolled patients suffered from longstanding UC (with a mean duration of 7.4 to 8.8 years by treatment group) and 71.4% of the patients showed a severe disease profile (modified Mayo Score of 7 to 9 at screening).

Phase 2a ABX464 maintenance study in ulcerative colitis – 15 patients completed 3rd year of treatment
In addition to the phase 2b maintenance results, Abivax recently also reported efficacy data from its ongoing phase 2a maintenance study in UC.

15 out of the 22 patients who were initially enrolled into the phase 2a maintenance study completed the third year of treatment with 50mg once daily oral ABX464 as of June 29, 2021.

Among the 13 patients who had centrally read endoscopies at the completion of year 3, 11 patients (85%) were still in clinical remission, of which 7 patients (54%) had an endoscopic remission (endoscopic subscore=0) and 11 patients had an endoscopic remission or improvement (endoscopic subscore=0 or 1).

The long-term safety profile of chronic ABX464 administration continues to be favorable.

[1] Clinical response (per Modified Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥2 points and ≥30% from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1.
[2] Treated patients as per protocol
[3] Intent-to-treat patient population
[4] Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.
[5] S. Vermeire et al.: Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial, Gastroenterology, March 2021

Launch of ABX464 global phase 3 clinical development program in ulcerative colitis
Abivax is currently preparing the launch of its global phase 3 clinical program with ABX464 in about 1,400 patients with moderate to severe UC, and is already engaged in discussions with the relevant regulatory authorities. The End-of-Phase-2 meeting with the US regulatory agency (FDA) is scheduled for Q4 2021. Subject to positive feedback from FDA and the subsequent scientific advice from the European Medicines Agency (EMA), scheduled for early Q1 2022, Abivax intends to start the recruitment and inclusion of the first patients as quickly as possible.

Success of Abivax late-breaking abstract presentation and live symposium at UEG Week Virtual 2021
Abivax's late-breaking abstract on its ABX464 phase 2b clinical data in UC was accepted as an oral presentation for this year's UEG Week Virtual conference and was presented by Prof. Séverine Vermeire, M.D., Ph.D, the principal investigator of the study, on Monday, October 4.

In addition, Abivax hosted an Industry Symposium at UEG Week Virtual 2021 on "ABX464, a novel anti-inflammatory drug-candidate for the treatment of ulcerative colitis". Presentations were given by the internationally renowned key opinion leaders Prof. Bruce Sands, M.D., M.S. and Prof. William Sandborn, M.D.

The late-breaking abstract presentation and the replay of the Industry Symposium are now publicly available on the Abivax website at **www.abivax.com/uegweek2021/**

About Abivax (www.abivax.com)
Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the physiological inflammation and immunological pathways to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, ABX464 to treat severe chronic inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

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