ABIVAX REPORTS EXCELLENT ONE-YEAR EFFICACY AND SAFETY DATA OF ABX464 PHASE 2B MAINTENANCE TRIAL IN ULCERATIVE COLITIS

Interim analysis demonstrates best-in-class clinical remission in 55.3% of 217 ulcerative colitis (UC) patients (full analysis set) after 48 weeks of once-daily oral 50mg ABX464

Moreover, in the subgroup of patients who had at least a clinical response after the 8-week induction study (n=121), 65.3% achieved clinical remission during the first year of maintenance treatment (full analysis set)

Endoscopic improvement and endoscopic remission at week 48 achieved by 61.8% and 33.6% of the patients respectively (full analysis set)

Good safety and tolerability profile supports chronic use of ABX464

Final preparations to launch ABX464 global pivotal phase 3 clinical program in UC ongoing, inclusion of first patients is expected in Q3 2022

PARIS, France, April 06, 2022 – 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 excellent results from the Interim Analysis of its phase 2b open-label maintenance study, including 217 patients who completed the one year of once-daily oral treatment with 50mg ABX464. These data emphasize ABX464's capacity to maintain and further improve patient-outcomes over time, as well as its continued favorable safety and tolerability.

Prof. William Sandborn, M.D., University of California San Diego School of Medicine and Co-Founder and Chief Medical Officer at Shoreline Biosciences, CA, said: *"The data of these patients treated for one year in this phase 2b maintenance study confirm the previous, positive observations made with ABX464 in the phase 2a. Currently, many patients stop responding or do not respond at all to available therapies. These results are encouraging as they suggest that ABX464 can induce short-term and, more importantly, maintain and even improve long-term efficacy in patients with in moderate to severe ulcerative colitis. The good safety and tolerability profile seen in the phase 2b is also very encouraging."*

Prof. Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York City, NY, added[1]: *"These maintenance data indicate that ABX464 may change the treatment paradigm for bio-naïve as well as refractory ulcerative colitis patients. ABX464 showed a solid and durable efficacy signal along with a good tolerability profile, which differentiates it from many other products on the market or in late-stage testing in UC. Beyond efficacy and safety, ABX464 also offers convenient once-daily oral administration."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"We are very pleased with the results of the phase 2b maintenance study with ABX464 after the first year of continued daily treatment. 65.3% of patients with at least a clinical response at the end of induction were in clinical remission after one year, which confirms the outcome of the phase 2a study with 66.7%. These are best-in-class results, demonstrating that the unique mechanism of action of our drug-candidate can induce high rates of durable clinical remissions in patients suffering from moderate to severe ulcerative colitis. Along with the maintenance data recently reported from our phase 2a trial in rheumatoid arthritis, these results further underpin the capacity of ABX464 to effectively address a broad range of chronic inflammatory diseases. Abivax will be initiating the ABX464 phase 3 program in UC soon, with a first patient to be included in Q3 2022. We want to make this potentially transformative drug-candidate available as quickly as possible to patients suffering from ulcerative colitis and possibly further chronic inflammatory indications."*

[1] Prof. Bruce Sands is a paid consultant for Abivax. He has not been compensated for any media work.

ABX464 phase 2b clinical maintenance study in ulcerative colitis

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 open-label maintenance study to evaluate the long-term safety and efficacy profile of ABX464 for up to two years.

The interim analysis after one year of treatment from the phase 2b open-label extension study in UC included all 217 patients who enrolled into the maintenance study with ABX464.

At week 48	**Full analysis set n=217** (Non-responder imputation)
Clinical remission[2]	n= 120 (55.3%)
Endoscopic improvement[3]	n=134 (61.8%)
Endoscopic remission[4]	n= 73 (33.6%)
Clinical response[5]	n=175 (80.6%)
Maintained clinical remission at week 48	n=38/52 (73.1%)

* Drop-outs (33 patients) were considered as treatment failures in the full analysis set.

Main efficacy endpoints according to clinical response status at end of the induction (week 8):

At week 48	**Patients with clinical response after induction n=121**	**Patients without clinical response after induction n=96**
Clinical remission	n=79 (65.3%)	n=41 (42.7%)
Endoscopic improvement	n=85 (70.2%)	n=49 (51.0%)
Endoscopic remission	n=46 (38.0%)	n=26 (27.1%)

Among the 217 patients who completed the first year of 50mg once-daily oral dosing with ABX464, 52 had entered the maintenance study already in clinical remission. 38 (73.1%) out of these 52 patients stayed in clinical remission during this first year of maintenance treatment. It is remarkable that 82/165 (49.7%) patients who were not in clinical remission at the end of induction achieved a *de novo* clinical remission during the first year of maintenance.

Furthermore, the clinical remission rate for patients who did not show at least a clinical response at the end of the induction phase was 42.7% (full analysis set) after 48 weeks of treatment, demonstrating that long-term administration of ABX464 provided substantial clinical benefits also for these patients.

33/217 (15.2%) of patients dropped out during the first 48 weeks of the phase 2b maintenance study. Worsening of UC was the primary cause of premature study discontinuation (10 patients - 30%). These patients were all considered as treatment failures in the full analysis set.

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 1,000 patients and volunteers treated with ABX464 so far.[6]

254 patients with moderate to severe active ulcerative colitis were enrolled into the phase 2b clinical study and dosed within 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 inhibitor treatments while the other 50% were refractory to conventional treatments. Endoscopies were read centrally and blinded by independent reviewers. The baseline disease characteristics were well balanced across all ABX464 dose groups

[2] Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.
[3] Endoscopic improvement is defined as endoscopic subscore ≤1.
[4] Endoscopic remission is defined as endoscopic subscore = 0.
[5] 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.
[6] 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

and the placebo group. Enrolled patients suffered from longstanding UC with an overall mean disease duration of 8.05 years and 71.4% of the patients showed a severe disease profile (baseline modified Mayo Score of 7 to 9 points).

Impact of the war in Ukraine on Abivax's phase 2b clinical study

The ABX464 phase 2b maintenance study in moderate to severe UC patients is the only trial currently conducted by Abivax on Ukrainian territory. The evaluation after 12 months of treatment had already been conducted for all Ukrainian patients prior to the outbreak of the war and are taken into account in the one-year results presented in this press release.

ABX464 phase 1 clinical studies

Abivax conducts four phase 1 studies with ABX464 in healthy volunteers, as part of the usual practice during late-stage clinical drug development.

The patient enrollment has been completed in all studies and the data analysis is progressing according to plan.

The currently available preliminary results are all supportive in advancing ABX464 into the pivotal phase 3 program.

ABX464 global pivotal phase 3 clinical program in ulcerative colitis

In December 2021 and January 2022 respectively, the US regulatory agency (FDA) as well as the European Medicines Agency (EMA) expressed their support in moving ABX464 into a pivotal phase 3 program in moderate to severe UC. The agencies raised no concerns regarding clinical safety, non-clinical safety, or CMC.

Both the FDA and EMA agreed with Abivax that progressing 25mg and 50mg (as the highest dose) into phase 3 testing is appropriate for both induction and the subsequent maintenance studies in UC. The agencies were supportive of Abivax's intention to drop the 100mg dose, as no additional therapeutic benefit could be observed with this higher dose.

Abivax is working with IQVIA, a global premier CRO, to jointly set-up and conduct these studies across Europe, the US, Japan and other global geographies. Given the current developments, Abivax decided that Ukraine, Russia and Belarus cannot be part of the ABX464 global phase 3 study program in UC.

Currently, more than 400 study sites, out of the targeted 600 sites, already confirmed their participation in the phase 3 trial and the enrollment of the first patient is planned for Q3 2022.

Acquisition of Prosynergia SARL

Abivax announces that it acquired on April 1, 2022, Prosynergia SARL, a Luxembourg biotech company, in order to strengthen the Abivax development portfolio, for an amount of EUR 3.25M. The terms of the transaction also include possible earn-out payments for a maximum additional amount of EUR 4M based on the potential evolution of Abivax's market capitalization.

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About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the body's natural immune machinery 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 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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