# Abivax reports long-lasting two-year efficacy and safety data from ABX464 ulcerative colitis Phase 2a maintenance study

Phase 2a open label maintenance results after second year of treatment confirm good safety profile and durable efficacy of 50mg once-daily oral ABX464

After the second year of continued treatment, 69% of patients were in clinical remission[1] and 94% benefited from a clinical response[2]

Readings of the endoscopies were performed centrally by independent reviewers; Median fecal calprotectin (31.6 µg/g) was in the normal range

Patient enrollment for ongoing Phase 2b ulcerative colitis trial is on track, with 69% (159/232) of patients randomized to date and recruitment expected to be completed by the end of 2020 and expected results in Q2/2021

Abivax is currently preparing all required steps to advance ABX464 into UC Phase 3

**PARIS, France, September 2, 2020 – 9:00 p.m. (CET)** – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, today announces two-year Phase 2a maintenance data of ABX464 in ulcerative colitis (UC), showing that 69% of the patients were in clinical remission and 94% benefited from a clinical response. The patients suffering from moderate-to-severe UC were all intolerant and/or refractory to at least one existing treatment prior to entering the ABX464 study. These data confirm good safety and efficacy results of ABX464 during the second year of treatment, which were already observed during the induction and first year of the maintenance study.

**Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said:** *"We are very excited about the two-year open label Phase 2a maintenance results, which provide further momentum for our clinical development efforts with ABX464 to address the high unmet medical need in UC. These recent findings reinforce the potential of ABX464 as a well-tolerated and efficacious once-daily oral therapy for patients with moderate-to-severe ulcerative colitis."*

Out of 32 patients included in the active or placebo arm of the initial induction phase, 22 were enrolled in the 50mg once-daily open label ABX464 Phase 2a maintenance study. 19/22 patients stayed on treatment for 52 weeks and 16/19 patients completed the second year of ABX464 maintenance treatment. Readings for all endoscopies were performed centrally by independent reviewers. The data showed that 11/16 (69%) patients were in clinical remission and 15/16 (94%) benefited from a clinical response. 7/16 (44%) had endoscopic remission consisting of complete disappearance of colon/rectum lesions (endoscopic Mayo score=0). Median fecal calprotectin, the key biological marker of UC disease activity, which was normalized during the first year of treatment, remained at 31.6 µg/g (normal levels are below 50 µg/g).

ABX464 was safe and well tolerated and there were no serious adverse drug reactions reported. No patients were prematurely discontinued due to adverse event during this second year of ABX464 treatment.

**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:** "*The safety and durability of clinical efficacy after two years of continued treatment of UC patients, intolerant or refractory to existing treatments, are very promising. Especially as the central and independent endoscopy readings after two years confirm the good one-year maintenance results, where endoscopies were read locally. We are very motivated to continue enrolling patients in the ongoing ABX464 Phase 2b induction and maintenance study and hope to be able to confirm the findings from the Phase 2a study."*

**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, added**: *"The two-year Phase 2a maintenance results confirm the potential of ABX464 to become a treatment option for UC patients who do not respond or stop responding to currently available treatments after a certain period of time, including biologics. This debilitating disease 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 provide these patients with an easily administered, once-daily oral, long-term effective therapeutic option."*

**Update on Abivax's Phase 2b induction and maintenance studies in moderate-to-severe UC patients:**

The study is currently ongoing in 15 European countries, Canada and the US, enrollment is on track with 69% (159/232) patients randomized to date in the induction study. Patient recruitment is expected to be completed by the end of this year with first top-level results to be communicated in Q2/2021. Out of 85 patients who completed the induction phase, only one patient did not roll over into the maintenance study, while the remaining 84 patients did. All patients in the maintenance study are receiving daily doses of 50mg oral ABX464, which shows a good safety profile consistent with previous studies. The clinical program in UC is Abivax's top priority and all necessary steps to further progress into Phase 3 studies are being prepared.

**Update on other ongoing and planned clinical trials with ABX464:**

Enrollment in the Phase 2a trials in rheumatoid arthritis is progressing well, with anticipated completion of recruitment by year-end. The Phase 2b/3 clinical trial in Covid-19 patients has been approved in all participating European countries and Brazil, where recruitment is

ongoing and expected to be completed in Q4/2020, subject to the evolution of the pandemic. Following the recommendations of leading KOLs, Abivax is planning to go straight into a pivotal Phase 2b/3 trial for Crohn's disease, which is expected to start recruiting beginning of 2021.

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**About Abivax**

Abivax, a clinical stage biotechnology company, is mobilizing the body's natural immune machinery to treat patients with autoimmune 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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[1] Stool frequency sub score = 0 or 1 and rectal bleeding sub score = 0 and endoscopy sub score = 0 or 1 (modified to exclude friability).

[2] Reduction in Modified Mayo Score ≥ 2 points and ≥ 30 % from baseline with an accompanying decrease in rectal bleeding sub-score ≥ 1 point or absolute rectal bleeding sub-score ≤ 1 point