Abivax publishes data of ABX464 induction and long-term maintenance phase 2a ulcerative colitis study in the prestigious journal “Gastroenterology"

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Peer-reviewed article confirms the quality and robustness of clinical data and the good safety and durable efficacy of once daily oral ABX464 in moderate to severe ulcerative colitis (UC) patients

Recruitment of subsequent phase 2b induction study in 254 patients with ABX464 in UC completed in December 2020 and top-line results are expected in Q2 2021

Abivax is preparing to move its lead drug-candidate ABX464 into a phase 3 clinical program in ulcerative colitis and to initiate a phase 2b/3 study in Crohn’s disease by year end

PARIS, March 3, 2021 – 06:30 p.m. (CET) – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company modulating the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, today announced that the induction and long-term maintenance follow-up results of the phase 2a clinical study with ABX464 for the treatment of moderate-to-severe ulcerative colitis have been published online in the renowned journal “Gastroenterology” . The peer-reviewed article scientifically confirms the quality and robustness of the data generated in Abivax’s randomized placebo-controlled, double-blind clinical study that consisted of an eight-week induction phase followed by an open-label long-term extension phase.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *“We are proud that “Gastroenterology” accepted the exciting results of our induction and long-term phase 2a maintenance study in moderate-to-severe ulcerative colitis patients with ABX464. We are very much looking forward to the top-line phase 2b induction results in UC that we expect to be available in Q2 2021 and we are confident that they will confirm the observations of the previous study in terms of safety and durable efficacy. Therefore, we are preparing to move our lead molecule into a phase 3 clinical program in ulcerative colitis and to initiate a phase 2b/3 clinical trial in Crohn’s disease. Abivax is placing great efforts into advancing the clinical development of ABX464, especially for the treatment of inflammatory bowel diseases, to provide a novel safe and long-lasting therapeutic option to patients suffering from these very disabling diseases.”*

Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, principal investigator of the study and first author of the publication, added: *“As principal investigator I am pleased to see that the scientific community confirmed the safety and durability of clinical efficacy of the phase 2a induction and long-term study results conducted with ABX464 in ulcerative colitis patients. I am now impatient to see the outcome of the phase 2b induction study and the subsequent maintenance trial to confirm these positive observations in a larger set of patients.*”

At the end of the eight-week induction of the phase 2a proof-of-concept clinical study in ulcerative colitis, 35% and 70% of patients in the ABX464 active group achieved clinical remission and clinical response versus 11.1% and 33.3% in the placebo group, respectively. Endoscopic improvement and remission were observed in 50% and 10% of patients receiving ABX464, respectively, versus 11.1% each for placebo.

To date, 15 patients in the phase 2a maintenance study are still on continued daily treatment and a total of 800 patients across different indications have so far been treated with ABX464.

ABX464 is currently being evaluated in a phase 2b UC clinical trial, a phase 2b/3 Covid-19 clinical trial and a phase 2a rheumatoid arthritis clinical trial. The initiation of a phase 2b/3 Crohn’s disease clinical trial as well as a phase 3 clinical program in ulcerative colitis are planned, subject to the results of the phase 2b clinical trial in UC.

About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is modulating 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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