



Abivax receives FDA feedback with guidance on advancing ABX464 into phase 3 clinical testing in ulcerative colitis

December 1, 2021

End-of-phase-2 response from the US regulatory agency (FDA) provides guidance and a path forward to advance ABX464 into a phase 3 clinical program in ulcerative colitis (UC)

PARIS, France, December 1, 2021 – 7:30 pm (CET) – 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 announced that the US Food and Drug Administration (FDA) recently provided valuable feedback in the context of the end-of-phase-2 meeting with guidance and a path forward to bring ABX464 into phase 3 clinical testing for the treatment of ulcerative colitis and subsequent potential marketing authorization submission and commercialization. This includes comments on study design, dose selection and the statistical analysis plan.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: “The FDA feedback on the end-of-phase-2 meeting with the regulator’s expectations and guidance for the ABX464 phase 3 study design in ulcerative colitis is a very important step for Abivax. We are now incorporating the FDA feedback into the study protocols and, following the scientific advice of the EMA, will work towards the final clinical study designs and operational set-up. 2022 will be an inflection point for Abivax taking our lead drug candidate ABX464 one important step further towards potential marketing authorization and commercialization, starting in North America, Europe and Japan.”

The scientific advice meeting with the European Medicines Agency (EMA) is scheduled for early Q1 2022. Taking into account the guidance from FDA and potential recommendations from EMA, Abivax intends to finalize the phase 3 study design and update its IND for ABX464 for the treatment of ulcerative colitis in Q1 2022. Subject to regulatory clearance, Abivax plans to enroll the first patient into its pivotal program in Q2 2022.

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_](https://twitter.com/ABIVAX_).

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