Abivax receives EMA Scientific Advice supportive of moving ABX464 into phase 3 clinical testing in ulcerative colitis

January 13, 2022

The responses from the European Medicines Agency (EMA) within the scientific advice meeting support moving 25mg and 50mg ABX464 into a phase 3 clinical program in ulcerative colitis (UC)

Abivax to present at the virtual J.P. Morgan Healthcare Conference on Thursday, January 13, 2022, at 12:00-12:40 pm ET (9:00-9:40 am PST and 6:00-6:40 pm CET)

PARIS, France, January 13, 2022 – 8:00 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 and cancer, today announced that the European Medicines Agency (EMA) provided their feedback in the context of the scientific advice meeting that supports advancing ABX464 into phase 3 clinical testing for the treatment of ulcerative colitis and subsequent potential marketing authorization submission and commercialization.

In November 2021, Abivax received written responses from the US regulatory agency FDA in the context of the End-of-Phase-2 meeting. This feedback was recently complemented by a separate FDA CMC Type C meeting, focusing on manufacturing aspects, as well as the responses from EMA to a scientific advice request.

The advice received supports moving ABX464 into a pivotal phase 3 program in ulcerative colitis, with no concerns raised regarding clinical safety, non-clinical safety, or CMC.

Both 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.

The FDA feedback and the EMA scientific advice are largely consistent and Abivax is currently reviewing suggested modifications, including comments on the study design, the potential for testing of a lower dose and the statistical analysis plan, to the pivotal study designs with its clinical and regulatory advisers. The final study protocols are planned to be submitted during the course of Q1 2022.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"Abivax is very happy with the outcomes of the regulatory consultations as they pave the way for finalizing an appropriate study design that will be crucial to confirm the benefit of ABX464 for the efficient and durable treatment of ulcerative colitis. Given the impressive phase 2a and phase 2b study results, especially with respect to long-term clinical remission data, we believe that our drug candidate can make a real difference to improve the lives of the many patients suffering from ulcerative colitis. I am looking forward to sharing our latest achievements and plans as part of my presentation at the J.P. Morgan Healthcare Conference with the investors and the pharmaceutical community."*

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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, 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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documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its registration document (Document d'Enregistrement Universel). Special consideration should be given to the potential hurtles of clinical and pharmaceutical development including further assessment by the company and regulatory agencies and ethics committees of preclinical, pharmacokinetic, carcinogenicity, toxicity, CMC, clinical data, Furthermore, these forward-looking statements, forecasts and estimates are only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Abivax disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law.

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