Abivax completes induction treatment of last patient in ABX464 phase 2b clinical study in ulcerative colitis

April 14, 2021

- 16-weeks induction treatment with ABX464 in phase 2b clinical study in ulcerative colitis completed for the 254 patients enrolled, with reduction of Total Mayo Score after 8 weeks as primary endpoint
- Top-line data of induction phase to become available in the second half of May 2021
- 48-weeks maintenance treatment with ABX464 in phase 2b clinical study in ulcerative colitis now fully enrolled, with top-line data to become available in Q1 2022
- Start of clinical phase 3 program in ulcerative colitis expected by year end
- KOL webcast scheduled on Tuesday, April 20, 2021 at 1:30 pm CEST with Prof. Bruce Sands, M.D., M.S. to discuss ulcerative colitis, existing and future treatment options, and current unmet needs

PARIS, France, April 14, 2021 – 6:30 p.m. (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 announces the completion of 16-weeks of induction treatment with different doses of ABX464 or placebo in its clinical phase 2b study for the treatment of moderate-to-severe ulcerative colitis (UC). Top-line data will become available in the second half of next month.

The first patient was enrolled into the double-blind, placebo-controlled, dose ranging phase 2b clinical trial with ABX464 in UC in August 2019 and recruitment of 254 patients was completed in December 2020. The last patient has now completed the 16-weeks induction treatment.

Ahead of the data read-out, the Company will host a webcasted key opinion leader (KOL) event on Tuesday, April 20, 2021 at 1:30 pm CEST (7:30 am EDT) with Prof. Bruce Sands, M.D., M.S., Chief of the Division of Gastroenterology at the Mount Sinai School of Medicine in New York, NY. Dr. Sands will discuss UC, current and future treatments and unmet needs, and Abivax's senior management will provide an update on the Company and the potential of ABX464 to become a safe and effective new treatment option.

Sophie Biguenet, M.D., CMO of Abivax, said: *"We are very much looking forward to communicating the results of the 16-weeks phase 2b induction study during the second half of May this year. These data will provide valuable information on the potential of ABX464 to become a well-tolerated, oral, easy-administrable, short- and long-term effective novel treatment option for the many patients suffering from moderate-to-severe UC. In parallel, the phase 2b maintenance study is continuing as planned and we are preparing for our phase 3 program in UC, expected to start by year end."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"The clinical phase 2b top-line read-outs in UC next month will give us more visibility on the strategic options for the Company. We will carefully evaluate and select the most attractive path forward to create shareholder value. Partnering with a large pharma or biotech company remains our strategic priority."*

The randomized, double-blind and placebo-controlled phase 2b induction trial had four arms: three once-daily oral ABX464 treatment groups (25 mg, 50 mg and 100 mg) and one placebo group. The study is conducted in 130 study centers in 15 European countries, Canada and the US under the leadership of its principal investigator, Prof. Séverine Vermeire, M.D., Ph.D., University Hospitals Leuven, Belgium. **Prof. William Sandborn, M.D., University of California San Diego Health**, serves as the principal investigator for the US.

All patients who completed the induction study had the option to enroll into the subsequent open-label maintenance study for up to two years to confirm the long-term safety and efficacy profile of ABX464. During this maintenance period, patients are being treated in an open label fashion with 50mg of once-daily oral ABX464. Abivax is using IQVIA as partner, a global premier CRO, to successfully conduct its clinical trials with ABX464 for the treatment of chronic inflammatory diseases.

At present, more than 800 patients have been treated with ABX464 across different indications, including UC. Some of these patients are in their fourth year of continuous daily dosing within the ongoing phase 2a maintenance study. Abivax reported excellent induction (after 8 weeks) as well as maintenance (after one and two-years) safety and efficacy data from the ABX464 UC phase 2a maintenance study with 50 mg once-daily oral ABX464 in patients with moderate-to-severe UC. After 12 months of treatment, 75% of the patients were in clinical remission. After the second year of continued treatment, 69% of patients were in clinical remission and 94% benefited from a clinical response.

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Abivax will host a virtual **KOL event as webcast** on **Tuesday, April 20, 2021 at 1:30 pm CEST** (7:30 am EDT), ahead of the data read-out of its ABX464 phase 2b clinical study in UC. **Prof. Bruce Sands, M.D., M.S.**, Chief of the Division of Gastroenterology at the Mount Sinai School of Medicine in New York City, NY, will provide expert information on existing and future treatment options for UC, including current unmet medical needs. In addition, Abivax will provide an update on the safety and efficacy of ABX464 as it applies to UC.

To participate in the webcast, please follow the weblink: https://media.rampard.com/20210420/

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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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