



## Abivax completes recruitment of ABX464 Phase 2b induction study in ulcerative colitis

November 30, 2020

- Recruitment of 232 patients completed ahead of schedule with minimal impact by the Covid-19 pandemic
- Top-line results expected to be available in Q2 2021
- Maintenance open label extension Phase 2b study in UC progressing well with 130 patients enrolled and expanded for a second year
- Preparation for pivotal Phase 2b/3 Crohn's disease and Phase 3 ulcerative colitis studies ongoing

**PARIS, November 30, 2020 – 7:00 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, announced today the completion of recruitment for its Phase 2b induction study for the lead candidate ABX464 for the treatment of patients with moderate-to-severe ulcerative colitis. This study exceeded industry standard recruitment rates for UC, during the Covid-19 crisis, by utilizing the experience, relationships and data built by working across many UC studies with sites, in tandem with innovative recruitment solutions. The randomization of the targeted 232 patients has been completed ahead of schedule, with minimal impact of the Covid-19 pandemic on the pace of recruitment. Top-line results of the Phase 2b UC induction study, conducted in 15 European countries, Canada and the US, are expected to be available in Q2 2021.

*“The completion of recruitment of the Phase 2b induction study in ulcerative colitis with ABX464, our lead clinical program, is a critical milestone for Abivax. We are very pleased that patients enrolled so rapidly into the trial, despite the Covid-19 pandemic.”, said Paul Gineste, Pharm D., VP Clinical Operations of Abivax, and he continued: “I would particularly like to thank our very committed investigators, our CRO, IQVIA, and our clinical team who made this possible, despite challenging circumstances. We are now looking forward to the high-level data that we expect will become available in Q2 2021.”*

**Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax,** added: *“With the financial resources of EUR 84m we secured over the past six months, Abivax is able to go full speed in advancing ABX464 into a pivotal Phase 2b/3 study in Crohn's disease and to prepare for the Phase 3 clinical program in UC. With ABX464 as a novel treatment with durable efficacy and a good safety profile observed in studies performed, we hope to make a real difference for patients suffering from the devastating consequences of inflammatory bowel diseases, as well as potentially other chronic inflammatory diseases.”*

The Phase 2b induction study in patients with moderate-to-severe UC (ABX464-103), enrolled the first patient in August 2019. In addition, Abivax initiated a companion long-term open-label maintenance study (ABX464-104) in which patients who have completed the induction study were eligible to continue the treatment to further investigate the long-term safety and efficacy profile of ABX464. 130 out of 132 patients, who completed the induction study, have been enrolled to date into the maintenance study that has been expanded for a second year.

The Company communicated positive results of the previous Phase 2a induction study in UC in September 2018, followed by additional positive data from the 12-month open label Phase 2a maintenance study presented at the UEG Conference in October 2019. Recently, these positive long-term data were further confirmed following [results from two years dosing of 50mg ABX464](#) in which 69% of patients were in clinical remission and 94% benefited from a clinical response.

**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: *“Given the promising results so far, I am looking forward to see data from this Phase 2b induction study and I hope that they will once again confirm the safety and durability of clinical efficacy of ABX464 in UC patients, already observed in the Phase 2a study. Ulcerative colitis is a very disabling disease for patients and the need for a durable and efficacious treatment is still very high.”*

**Alistair Grenfell, President, IQVIA EMEA,** said: *“IQVIA is proud to have been selected as the CRO partner of Abivax for the ABX464 induction and maintenance studies in ulcerative colitis. We are delighted to see the use of our unique CORE Powered capabilities helped Abivax complete recruitment ahead of plan and despite the Covid-19 pandemic challenges. We look forward to continuing the study with Abivax and the investigational sites to manage the clinical data and deliver high quality study results in Q2 2021.”*

### Update on Abivax's additional ongoing clinical trials

Abivax's Phase 2a proof of concept clinical trial with ABX464 in rheumatoid arthritis is progressing according to plan with top-line results of the induction study to be communicated in Q2 2021.

The Phase 2b/3 clinical trial of ABX464 in Covid-19 patients is ongoing in Europe and Latin America and top-line results are expected in Q1 2021, subject to the evolution of the pandemic.

The clinical Phase 1/2 study with Abivax's second clinical candidate, ABX196, in hepatocellular carcinoma which is being conducted in the US is also progressing, despite the Covid-19 situation.

## About Abivax ([www.abivax.com](http://www.abivax.com))

Abivax, a clinical stage biotechnology company, is mobilizing the body's natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment C (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](http://www.abivax.com). Follow us on Twitter @ABIVAX\_.

## About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry. Formed through the merger of IMS Health and Quintiles, IQVIA applies Human Data Science — leveraging the analytic rigor and clarity of data science to the ever-expanding scope of human science — to enable companies to reimagine and develop new approaches to clinical development and commercialization, speed innovation and accelerate improvements in healthcare outcomes. Powered by the IQVIA CORE™, IQVIA delivers unique and actionable insights at the intersection of large-scale analytics, transformative technology and extensive domain expertise, as well as execution capabilities. With approximately 67,000 employees, IQVIA conducts operations in more than 100 countries.

IQVIA is a global leader in protecting individual patient privacy. The company uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while generating and analyzing information on a scale that helps healthcare stakeholders identify disease patterns and correlate with the precise treatment path and therapy needed for better outcomes. IQVIA's insights and execution capabilities help biotech, medical device and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviors and scientific advances, in an effort to advance their path toward cures. To learn more, visit [www.iqvia.com](http://www.iqvia.com).

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