ABIVAX TREATS FIRST PATIENT IN PHASE 2B/3 ABX464 COVID-19 CLINICAL TRIAL

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First patient treated in "miR-AGE" trial at University Hospital Center in Nice (CHU Nice)

50 study sites and 1,034 high-risk patients to participate in the European and Latin American placebo-controlled trial

ABX464 works via unique triple action: antiviral, anti-inflammatory and tissue repair

Easy, once daily oral administration allows inclusion of hospitalized as well as non-hospitalized COVID-19 patients

Results from this study expected by year-end

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PARIS, France, July 02, 2020 – 07:30 a.m. (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a late stage clinical biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, announces today that the first patient has been treated in its Phase 2b/3 study of ABX464 in COVID-19 patients at the University Hospital Center in Nice, France (CHU Nice).

The randomized, double-blind, placebo-controlled miR-AGE study investigates the effect of early treatment (at point of diagnosis) in 1,034 COVID-19 elderly or high-risk patients. The main goal of the trial is to measure the potential of ABX464 to limit viral replication as well as the severe inflammation that leads to acute respiratory distress syndrome (ARDS). Abivax has already received clearance for the study from the regulatory authorities in France and Germany as well as in the UK, Italy and Brazil and expects authorization to follow in Spain and additional Latin American countries with high infection rates, including Mexico, Chile and Peru in due course.

Prof. Hartmut Ehrlich, M.D., CEO of Abivax, said: "*We are pleased that the first patient in our miR-AGE trial has been treated and that recruitment and treatment at further sites in Europe and Latin America can now proceed swiftly. After the approval of the regulators in Brazil, additional regulatory approvals in Latin American countries, where the epidemic has still not reached its peak, are expected to follow soon. We expect first top-line results from miR-AGE by the end of the year. Enrollment in our other clinical trials is now back on track with more than half (122/232) of the patients randomized in the ulcerative colitis Phase 2b trial and with recruitment in the Phase 2a trial in rheumatoid arthritis and the US Phase 1/2 trial in hepatocellular carcinoma progressing as well. With non-dilutive funding provided by Bpifrance and Société Générale, Abivax's projects are fully financed until early 2021 and discussions for further, preferably non-dilutive financial options are ongoing.*"

"*The treatment of the first patient in the miR-AGE trial is an important milestone for Abivax,*" added **Philippe Pouletty, M.D., Chairman of the Board of Abivax and CEO of Truffle Capital**. "*While further study centers in Europe are being initiated, we also continue to expand the trial in additional Latin American countries. The already available regulatory and national ethics committee clearance in Brazil make a recruitment start in July realistic, as we are only missing the local ethics approvals. Furthermore, the ongoing preparation of filing in Mexico, Chile and Peru are very important, as the pandemic is still very active in these countries. While we are confident that ABX464 may have a positive impact by reducing the severity of COVID-19 sequelae, we remain prudent on expectations for the miR-AGE trial given the complexities surrounding treatment of COVID-19 disease. Progressing ABX464 development in chronic inflammatory diseases remains Abivax's corporate priority.*"

Eric Cua, M.D., Infectiologist at the University Hospital Center (CHU) of Nice, said: "*As the principal investigator at the CHU in Nice, I am glad that the first patient has been treated and I am very much looking forward to evaluating whether early treatment with ABX464 will have a positive effect in COVID-19 patients. ABX464's unique triple mode of action could potentially limit the replication of SARS-CoV-2 virus, prevent and treat the cytokine storm or hyper-inflammation – and the ensuing acute respiratory failure syndrome – as well as limit long-term lung injury through tissue repair. Due to ABX464's easy, once-daily oral administration, we can include hospitalized as well as non-hospitalized COVID-19 patients in this trial. We hope that the findings in this placebo controlled and randomized trial bring us one step closer to a potent treatment for this disease in order to protect especially high-risk patients and avoid tense situations in hospitals and intensive care units in the future.*"

ABX464 has already demonstrated impressive efficacy in a Phase 2a trial in another severe inflammatory disease, ulcerative colitis (UC). In this trial, specifically, potent anti-inflammatory effects and tissue healing were observed. The results in UC patients together with the unique molecular mechanism of action of ABX464 support the rationale to use the drug candidate to treat the cytokine storm and hyper-inflammation syndrome observed in COVID-19 patients. Hyper-inflammation in the lung is the primary cause of the respiratory distress and potential death in COVID-19 patients.

ABX464's molecular action has been shown to upregulate a micro-RNA, miR-124, which is a "physiological brake" on inflammation. It works by down-regulating the multiple chemo- and cytokines involved in the COVID-19 cytokine storm, including TNF alpha, IL-1 beta, G-CSF, IL-6, MCP-1 and IL-17. In addition, unlike other potent anti-inflammatory agents that specifically target single cytokines, ABX464 has not been associated with increased vulnerability to opportunistic infections or a damping down of the immune system.

Furthermore, in previous clinical testing ABX464 has been shown to have antiviral effects against HIV and it is the first therapeutic candidate ever in development that reduced HIV reservoirs in patients. More recently, ABX464 demonstrated a marked antiviral effect, inhibiting SARS-CoV-2 (COVID-19) replication in reconstituted human respiratory epithelium model.

Financing for this Phase 2b/3 trial, as well as manufacturing scale-up, additional clinical and other development costs is provided by the French investment bank Bpifrance, with 36 million EUR in non-dilutive funding. In addition, Abivax recently received 5 million EUR in non-dilutive financing from Société Générale in the form of a loan guaranteed by the French state. Abivax's operations and ongoing clinical study programs are fully financed until early 2021.

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About Abivax

Abivax, a clinical stage biotechnology company, is mobilizing the body's natural immune machinery to treat patients with autoimmune 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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