Abivax announces German regulatory approval of ABX464 Covid-19 Phase 2b/3 COVID-19 clinical trial

May 25, 2020

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Second regulator to approve "miR-AGE" Phase 2b/3 trial after clearance of French authorities (ANSM)

1,034-patient placebo-controlled trial to test oral ABX464's triple effect in COVID-19 patients: antiviral, anti-inflammatory and tissue repair

Bpifrance provided €36 million non-dilutive funding for ABX464 COVID-19 development

First patients expected to be enrolled shortly and additional European regulatory approvals are in process

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PARIS, France, May 25, 2020 – 07:00 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 German regulatory authority for drugs and medical products, BfArM (Bundesinstitut für Arnzeimittel und Medizinprodukte), has approved its Phase 2b/3 study of ABX464 in COVID-19 patients.

The randomized, double-blind, placebo-controlled study is investigating early treatment (at diagnosis) in 1,034 COVID-19 elderly or high-risk patients (miR-AGE trial). The main goal of the trial is the potential of ABX464 to block viral replication in these patients as well as the severe inflammation that leads to acute respiratory distress syndrome (ARDS). Abivax recently announced clearance by the French regulatory authorities (ANSM) and the ethics committee for this pan-European COVID-19 study.

Financing is being provided by the French investment bank Bpifrance, with €36 million in non-dilutive funding (€20.1. million grant, and €15.9 million loan refundable upon success) for this Phase 2b/3 trial, as well as manufacturing scale-up, additional clinical and other development costs.

Prof. Hartmut Ehrlich, M.D., CEO of Abivax, said: "*We are pleased to receive such swift approval from German regulators, following quickly on the one from France. We are preparing for additional European regulatory authorities in countries that have been particularly affected by COVID-19, such as Spain, Italy, Belgium and Great Britain, to rapidly approve the miR-AGE trial of ABX464 to treat high-risk COVID-19 patients. With financing granted by Bpifrance, we are planning to enroll the first patients by the end of May and expect top-line data by the end of this year. In parallel, we will prepare to swiftly scale up manufacturing and apply for market approval, should the miR-AGE trial confirm ABX464's clinical benefit in COVID-19 patients. Of course, Abivax also is continuing its other clinical trials, first and foremost the Phase 2b study with ABX464 in ulcerative colitis and the Phase 2a study of ABX464 to treat rheumatoid arthritis. Finally, we are continuing to entertain active discussions to secure further, preferably non-dilutive, financing.*"

PD Christoph Boesecke, M.D., Senior Physician Infectiology at the University Hospital Bonn and leading clinical investigator for the miR-AGE clinical trial in Germany, said: "We *are eager to initiate Abivax's clinical trial to assess whether early anti-inflammatory treatment with ABX464 will improve patients' outcomes. ABX464 is a late-stage development compound with a novel, first-in-class mechanism of action. Specifically, the overexpression of miR-124, a microRNA that is leading to anti-viral activity and down-regulation of important pro-inflammatory chemo- and cytokines like TNF alpha, IL-6, MCP-1 and IL-17. With its transformational efficacy data in patients with moderate-to-severe ulcerative colitis as well as its favorable safety profile in more than 300 volunteers and patients with HIV or ulcerative colitis, we believe that ABX464 should be urgently tested against placebo plus standard of care in this robust, double-blinded and sufficiently powered miR-AGE clinical trial in COVID-19 patients before they develop an acute respiratory distress syndrome.*"

ABX464 is a convenient once-daily orally available small molecule with a unique mechanism of action, upregulating a microRNA, miR-124, with anti-inflammatory, antiviral and tissue repair properties. With its triple effect, the molecule is uniquely positioned to potentially limit replication of SARS-CoV-2 virus, prevent, and treat the cytokine storm, hyper-inflammation, and acute respiratory failure syndrome as well as potentially limit long-term lung injury. ABX464 is the only molecule known to have this triple effect.

Because ABX464 is orally available, it enables the inclusion of hospitalized and, importantly, non-hospitalized COVID-19 patients in the clinical trial. Thus, high-risk patients will be treated earlier, upon diagnosis. This could save lives by preventing progression of the disease to more severe forms and relieve the resulting burden on hospitals.

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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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