



€36 million non-dilutive funding from Bpifrance for ABIVAX' ABX464 Covid-19 program

May 15, 2020

Funding covers 1,034-patient placebo-controlled ABX464 Phase 2b/3 COVID-19

miR-AGE trial, manufacturing scale-up and additional development costs related to the potential filing of ABX464 Marketing Authorization Applications

ABX464's triple effect well suited for COVID-19 treatment evaluation in clinical trial: antiviral, anti-inflammatory and tissue repair

ABX464 miR-AGE Phase 2b/3 trial was approved by ANSM and Ethical Committee CPP and is expected to enroll first patients soon

Additional European regulatory approvals in process

PARIS, France, May 15, 2020 – 10:30 p.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 Bpifrance (Copil, SGPI) approved a €36 million non-dilutive funding (€20.1 million grant, and €15.9 million loan refundable upon success) for its Phase 2b/3 trial of ABX464 in high-risk patients with COVID-19 as well as manufacturing scale-up and additional clinical and other development costs.

Philippe Pouletty, M.D., Founder and Chairman of the Board of Abivax and CEO of Truffle Capital, said: *"We are very pleased to announce this approval of a €36 million non-dilutive funding for the COVID-19 miR-AGE Phase 2b/3 study and ABX464 pharmaceutical and clinical development program, to potentially provide a novel treatment option for patients with COVID-19. We would like to thank Bpifrance, the Secrétariat Général pour l'Investissement and their outstanding teams that worked hard with Abivax to speed-up their in-depth evaluation and decision process. Our gratitude also goes to ANSM, the ethics committee, clinicians and our partners that joined in this special effort. Our goal is to now implement the 1,034 patients ABX464 miR-AGE trial as rapidly as possible and, if we get positive results, bring with no delay ABX464 to the market and manufacture sufficient drug product for patients."*

Prof. Hartmut Ehrlich, M.D., CEO of Abivax, said: *"The orally available ABX464, with its unique mechanism of action resulting in a triple effect - antiviral, anti-inflammatory, tissue repair - may have the potential to improve the outcome for patients with COVID-19. Now, with funding for the clinical and development program in place, we are rapidly initiating this rigorously designed clinical trial to hopefully translate the promising features of ABX464 into tangible clinical benefits for the patients. If miR-AGE is successful, we will work with regulators to make ABX464 available as quickly as possible, including rapid manufacturing scale-up. In parallel, we continue the ABX464 Phase 2b trial for ulcerative colitis, Phase 2a for rheumatoid arthritis, and the preparation of a Phase 2b trial for Crohn's disease. Securing this financing from Bpifrance is a first major step towards funding Abivax for the next 18-24 months, preferably non-dilutive."*

Bpifrance is the investment bank of the French state, supporting entrepreneurial activities that are in the public interest. The financing will allow to fund the consortium led by Abivax (including Nice University Hospital) in order to conduct the ABX464 COVID-19 miR-AGE clinical study, as well as ABX464 manufacturing scale-up and additional clinical and other development costs. The provision of funding is planned to take place over a period of one year, including expenditures since February 1, 2020, to be implemented as soon as the administrative steps have been completed. The funding consists of €20.1 million in grants and €15.9 million in refundable loans, which Abivax would repay after ABX464 reaches commercial stage. Specific agreements with regards to this financing will be finalized between Abivax and Bpifrance in the coming weeks.

Abivax recently announced [clearance by the French regulatory authorities \(ANSM\) and the ethics committee to conduct the randomized, double-blind and placebo-controlled miR-AGE trial](#) in 1,034 elderly or high-risk COVID-19 patients. About 50 French and European clinical study sites are expected to investigate the clinical benefits of Abivax' lead development candidate ABX464.

ABX464 is a small molecule with a unique mechanism of action, upregulating a microRNA, miR-124, [with antiviral, anti-inflammatory and tissue repair properties](#), and with convenient once-daily oral dosing. 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. However, given the complexity and rapid development of COVID-19 disease, there is no certainty that any medical benefit can be shown in the miR-AGE trial.

The oral dosage form of ABX464 enables the inclusion of hospitalized and, importantly, non-hospitalized COVID-19 patients into the clinical trial, and high-risk patients will be treated early following diagnosis. The design of the miR-AGE trial should ensure the generation of scientifically and medically valid conclusions. Provided patient recruitment can be achieved and the trial is successful, MAA (market authorization application) filings will be done in France, Europe and globally.

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.

About Truffle Capital

Established in 2001, Truffle Capital is an independent European Venture Capital company, specializing in breakthrough technologies in life sciences (BioTech and MedTech) and in FinTech and InsurTech fields. Truffle Capital's mission is to support the creation and development of young innovative companies able to become tomorrow's leaders. More information: www.truffle.com – Twitter: @trufflecapital

About Bpifrance

Bpifrance helps stimulate French business' growth by offering loans, providing guarantees and awarding buyer and supplier credit to encourage business abroad. It finances over 80,000 companies.

More information at www.bpifrance.fr.

About the Secrétariat Général pour l'Investissement (SGPI)

SGPI is in charge, under the authority of the Prime minister, of the Programme d'Investissement d'Avenir (PIA).

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