



Abivax provides business update on most recent achievements and announces positive results of annual ordinary and extraordinary general meeting

June 22, 2020

Brazilian Health Regulatory Agency approves Phase 2b/3 study miR-AGE of ABX464 in COVID-19 patients

miR-AGE study has been approved by French and German regulators, and most recently by the British and Italian regulatory authorities

French government announced the selection of six COVID-19 projects to finance with a total of 78m EUR, with Abivax to receive 36m EUR

Final agreements for the 36m EUR funding have been signed with Bpifrance

Patient enrollment in ulcerative colitis Phase 2b trial post COVID-19 getting back on track, with 113 of 232 randomized to date

All resolutions presented during the general meeting were adopted

PARIS, France, June 22, 2020 – 07:00 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, today provides an update on its most recent clinical and financial achievements and developments and announces the positive results of the annual ordinary and extraordinary general meeting held on June 19, 2020.

The Brazilian Health Regulatory Agency (ANVISA - Agência Nacional de Vigilância Sanitária) approved the [randomized, double-blind and placebo-controlled miR-AGE trial](#) in high-risk COVID-19 patients. The study, already approved in [France](#) and [Germany](#), will now be expanded to Brazil, where the number of new infections is still increasing rapidly. Approval for the miR-AGE trial has also been granted by the British Medicines and Healthcare Products Regulatory Agency (MHRA) and the Italian Medicines Agency (AIFA), with approval in Spain expected shortly.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *“By expanding the miR-AGE study to Brazil, currently the pandemic’s most active country, we hope to be able to provide an efficient therapeutic option for the treatment of high-risk COVID-19 patients. We are also advancing the approval process in additional Latin American countries that are heavily affected by the rapid expansion of the pandemic. In parallel, patient recruitment is progressing according to our expectations for our ongoing clinical trials with ABX464, i.e. the Phase 2b in ulcerative colitis and Phase 2a in rheumatoid arthritis, as well as the US Phase 1/2 trial with ABX196 to treat hepatocellular carcinoma.”*

Prof. Jorge Kalil, M.D., Ph.D., Head of Immunology at the University Hospital in Sao Paulo and miR-AGE overall study coordinator in Brazil, added: *“We are eager to start the miR-AGE trial in Brazil and to test this innovative and promising drug candidate for the benefit of all countries and patients affected by the COVID-19 pandemic, which is still globally present. We hope to see a positive effect from the early treatment with ABX464 in reducing the severity of the disease by inhibiting viral replication, preventing hyper-inflammation and thus the potential deadly acute respiratory distress syndrome and also by limiting potential long-term lung injury in patients.”*

Philippe Pouletty, M.D., Chairman of the Board of Abivax, said: *“We are proud that Abivax’s ABX464 was selected by the French government as a promising drug candidate for treatment of COVID-19. We wish to thank Bpifrance, the Secrétariat Général pour l’Investissement (SGPI) and the French government for their backing and support of Abivax. At the same time, 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.”*

With regards to the financial situation of the Company, the final agreements with Bpifrance, the investment bank of the French state, have been signed following [the French government’s selection of six development projects](#) for a potent COVID-19 treatment. These projects will be financed with a total of 78m EUR by the French state, of which Abivax will receive 36m EUR in non-dilutive funding for its 1,034-patient ABX464 Phase 2b/3 COVID-19 (miR-AGE) trial, manufacturing scale-up as well as additional development costs related to other ABX464 studies for the potential filing of ABX464 Marketing Authorization Applications (MAA).

Abivax recently also announced a further 5m EUR non-dilutive financing from Société Générale in the form of a loan guaranteed by the French state (PGE - Prêts Garantis par l’Etat).

Didier Blondel, Chief Financial Officer of Abivax, said: *“With the official signing of the final contracts with Bpifrance and the loan recently granted by Société Générale, Abivax’s cash resources will fully finance the corporate objectives and current development plans until early 2021. We currently plan to continue to focus on sourcing additional non-dilutive financing options for the longer term.”*

The Company also announces today that it held its annual ordinary and extraordinary general meetings on June 19, 2020 behind closed doors, under the chairmanship of Dr. Philippe Pouletty, Chairman of the Board of Directors and without the physical presence of its shareholders due to COVID-19 social distancing practices.

All resolutions presented by the Board of Directors were adopted, including the compensation policy applicable to the Chief Executive Officer and the directors. Details of the voting results on all resolutions will be available on the company website.

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 – Mnémon: 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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