Abivax follows DSMB recommendation to stop the phase 2b/3 miR-AGE Covid-19 clinical trial due to lack of efficacy

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The Data Safety and Monitoring Board (DSMB) confirmed ABX464 was safe and well tolerated in 383 high-risk Covid-19 patients

Lower than expected rate (10.1%) of progression to severe disease or death with no difference between ABX464 and placebo groups

Decision has no impact on ABX464 development in chronic inflammatory indications

ABX464 top-line clinical data expected in Q2 2021 for phase 2b ulcerative colitis trial and phase 2a rheumatoid arthritis trial

PARIS, March 5, 2021 – 08:00 p.m. (CET) – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company modulating the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, announces today that it is halting the miR-AGE phase 2b/3 clinical trial in high-risk Covid-19 patients after the independent Data Safety and Monitoring Board (DSMB) recommendation for lack of efficacy.

The multinational miR-AGE ABX464 phase 2b/3 clinical trial (ABX464-401), has already recruited 500 high-risk Covid-19 patients out of the planned 1,034 and has been declared "Research National Priority" by the French government in December 2020. The study has a robust randomized, double-blind and placebo-controlled design to test whether ABX464 could prevent the development of severe Covid-19 disease in the participants. The DSMB recommendation is based on a planned, interim analysis evaluating data of 305 high-risk Covid-19 patients who completed the study period. The comparison of the data generated in the patient group treated with ABX464 versus the placebo group, did not show a difference in the rate of severe disease between the placebo group and the ABX464 group. Importantly, ABX464 was well tolerated and safe in these high-risk Covid-19 patients.

Eric Cua, M.D., infectious disease specialist at the University Hospital Center (CHU) of Nice and principal coordinator of the miR-AGE trial in France, said: *The very well designed and conducted miR-AGE study aimed at preventing severe acute disease characterized by hyperinflammation and cytokine storm. Thanks to the robust study design, we can rely on the outcome of the interim analysis that showed the futility of the trial. The analysis also confirms the good safety of ABX464. The low rate of severe disease in this high-risk population was unexpected, however, it is good news about the prognosis of high risk Covid-19 patients with the current standard of care and with emerging variants."*

Prof. Jorge Kalil, M.D., Ph.D., Professor and Head of Clinical Immunology and Allergy at the University Hospital Center in São Paulo and national coordinator of the miR-AGE study in Brazil, added: *"As an immunologist, I am puzzled by the outcome of the interim analysis, as ABX464 addresses both the viral and inflammatory aspects of the disease. However, we recognize that Covid-19 is a novel, hyper-acute and complex disease that involves various viral and inflammatory pathways, plus the coagulation system, which are still not fully understood. The participation of clinical research teams across Brazil within this multinational trial was a very enriching experience that will be valuable for future clinical studies."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"The miR-AGE trial was set up based on a scientifically sound rationale and it was robustly designed with the input of a highly experienced steering committee in order to evaluate the safety and efficacy of ABX464 in preventing severe Covid-19 disease and death in high-risk patients. Although this is a disappointing outcome, the good safety and tolerability data in this fragile population will be very useful going forward, and I would like to thank all investigators, healthcare personnel, patients and Bpifrance for their active involvement in the study. ABX464 has been shown to be highly efficacious in treating "chronic" inflammation according to clinical, endoscopic and histological endpoints in ulcerative colitis, as confirmed by the phase 2a data published this week in the peer-reviewed "Gastroenterology" article . Therefore, this outcome in "hyper-acute" Covid-19 disease has no impact on ABX464 potential to be successful in chronic inflammatory disease."*

About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is modulating the body's natural immune machinery to treat patients with chronic inflammatory 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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