

# Abivax's Covid-19 phase 2b/3 miR-AGE trial with ABX464 declared Research National Priority by the French government's clinical trial council

*Research National Priority has priority for patient enrollment in clinical trials for an accelerated review and approval process with the French regulatory authorities*

*Effective Covid-19 treatments very much needed because optimal vaccination coverage of millions of individuals and public acceptance will take time*

*ABX464 mechanism of action not expected to be impacted by viral mutations*

*Pivotal phase 2b/3 Covid-19 trial results expected in Q2 2021 and ABX464 manufacturing scale-up is ongoing to meet potential demand from commercialization in 2021*

**PARIS, December 22, 2020 – 7:30 p.m. (CET) –** Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, today announced that the Company’s ongoing ABX464 phase 2b/3 trial in high-risk Covid-19 patients (miR-AGE) has been declared a “Research National Priority” by the French government steering committee for therapeutic clinical trials and other research (CAPNET). This committee, advised by the REACTing Scientific Council, has been created by the French government to identify the most promising and impactful Covid-19 clinical trials in order to help investigators focus their patient recruitment and to foster the swift availability of high-level study results. Clinical trials declared Research National Priority and their sponsors have access to an accelerated regulatory review and approval process conducted by the French regulatory authorities (ANSM) and the French Ethics committee

(CPP). The Research National Priority designation also incentivizes clinical investigators to prioritize enrollment of their patients in these clinical trials and may provide institutional financing of these clinical studies.

**Philippe Pouletty, M.D., Chairman of the Board of Abivax and CEO of Truffle Capital, said:** *“We are proud to be part of the national and international efforts to fight Covid-19 and that the French government's Covid-19 scientific council decided to designate the miR-AGE trial with ABX464 drug candidate a Research National Priority, given ABX464 promising characteristics for early treatment of infected patients. Abivax is devoting significant efforts to this major international clinical trial and simultaneously accelerating ABX464 manufacturing scale-up for potential 2021 commercialization. The strong support of Bpifrance and GCI has been critical in providing the necessary resources to our team and partners. We cannot predict the efficacy of ABX464 in Covid-19 patients before miR-AGE trial results are available. However, given the major impact of Covid-19 pandemic, it is our duty to anticipate the commercial availability of ABX464 in order to be ready to obtain a marketing*

*authorization and launch the product in 2021, should the miR-AGE trial provide positive results.”*

Abivax’s lead drug-candidate ABX464 has shown in clinical and preclinical studies that it may have a potentially beneficial triple effect for the treatment of elderly and high-risk Covid-19 patients, including an antiviral and anti-inflammatory effect as well as tissue repair properties. With its unique molecular mechanism of action (upregulation of miR124), and convenient oral dosing, ABX464 can be used in patients upon diagnosis and has the potential to prevent and treat cytokine storm and hyper-inflammation, which can lead to acute respiratory distress syndrome (ARDS) and death of Covid-19 patients. Should the results from the ongoing phase 2b/3 Covid-19 study expected for Q2 2021, be positive, Abivax will immediately seek accelerated marketing approvals in the major markets in 2021, and it is preparing for manufacturing scale-up and potential commercialization of ABX464.

ABX464 is mainly developed to treat patients with chronic inflammatory diseases and is currently in clinical testing in a phase 2b study in

ulcerative colitis (UC), a phase 2a study in rheumatoid arthritis (RA) and a pivotal phase 2b/3 trial in Crohn's disease will commence in 2021. Topline results of the ongoing trials in UC and RA are expected in Q2 2021. So far, over 700 patients have been treated with ABX464 showing a good safety and tolerability profile. Some patients have been on daily treatment with ABX464 for over three years in the ongoing phase 2a open label extensions study in UC, with promising long-term efficacy results after 2 years of continued treatment. The Company is currently preparing to move its clinical trial program with ABX464 in UC into a pivotal phase 3.

**Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, added:** *“Despite the recent approvals for Covid-19 vaccines, there are still many unknowns and effective treatments for Covid-19 infection are needed more than ever. In addition to the logistical challenges in vaccinating billions of people, vaccines are currently not mandatory and public acceptance of vaccination may take time. So effective treatment options for infected patients are highly desirable. In addition, the duration of vaccine protection is still unknown and mutations may emerge – this means we*

*still urgently need to decrease the likelihood of evolution towards severe life-threatening disease in Covid-19 infected patients. As miR-AGE is now a Research National Priority, we hope that the French study centers will be able to recruit more high-risk patients to catch up with other European and Latin American countries. These patients will then be able to potentially benefit from ABX464's triple effect, along with its convenient and easy oral administration, which also may avoid the need to be hospitalized and ease the burden on our healthcare systems.”*

### **About Abivax ([www.abivax.com](http://www.abivax.com))**

Abivax, a clinical stage biotechnology company, is mobilizing the body's natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment C (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](http://www.abivax.com). Follow us on Twitter @ABIVAX\_.

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*of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its registration document (Document d'Enregistrement Universel). Furthermore, these forward-looking statements, forecasts and estimates are only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Abivax disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law.*

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