# ABX464 inhibits replication of SARS-CoV-2 (COVID-19) in reconstituted human respiratory epithelium model

May 14, 2020

## ABX464 is the only drug candidate with a potential triple action for COVID-19 treatment: antiviral, anti-inflammatory and tissue repair

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**ABX464, as assessed by RTqPCR, inhibits *in vitro* viral replication of SARS-CoV-2 (COVID-19)**

**Simultaneously, Abivax receives ANSM and CPP clearance[1] to test ABX464 as promising COVID-19 therapeutic candidate in Phase 2b/3, randomized, 1,034 patient, miR-AGE clinical trial**

**COVID-19 patients die from acute respiratory failure resulting from viral replication inducing pulmonary hyper-inflammation or longer-term fibrosis**

**ABX464 is the sole drug candidate with such promising triple activity, inhibition of SARS-CoV-2 replication shown *in vitro*, inflammation reduction and tissue repair shown in ulcerative colitis patients**

**ABX464 would meet U.S. NIH/NIAID COVID-19 strategic priorities for novel drugs: antiviral, anti-inflammatory, tissue repair, oral administration, convenient once-daily administration**

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**PARIS, France, May 14, 2020 – 06:00 a.m. (CET)** – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, announces today that ABX464 inhibits replication of SARS-CoV-2 in an *in vitro* reconstituted human respiratory epithelium model, as assessed by Transepithelial electrical resistance and RTqPCR. ABX464 has already been shown to be an effective drug candidate in a severe inflammatory disease, ulcerative colitis. miR-124 specific upregulation by ABX464 can explain the triple effect of the drug candidate on inhibiting viral replication, down-regulation of cytokines that induce inflammation and tissue repair.

The breakthrough scientific data Abivax is reporting today make ABX464 a unique potential treatment for COVID-19 patients. Given the current pandemic and patient's excessive inflammatory response to viral replication as the primary cause of acute respiratory distress syndrome (ARDS) and death of COVID-19 patients, ABX464 with its convenient oral administration and its potential unique triple mode of action, will be urgently tested in a European clinical trial as a potential new treatment to:

**- Prevent and reduce inflammation**, as already demonstrated in another severe inflammatory disease, ulcerative colitis. Indeed, ABX464 has been shown to upregulate miR-124[2], a "natural brake" of inflammation. miR-124 down-regulates the multiple chemo- and cytokines involved in the COVID-19 cytokine storm, including TNF alpha, IL-1 beta, G-CSF, IL-6, MCP-1 and IL-17.

**- Reduce viral replication**, mediated by RNA quality control and miR-124 induced inhibition of dynamin 2, a key component necessary for viral replication.

**- Promote tissue repair** and **decrease pulmonary fibrosis**.

By binding to the Cap Binding Complex (CBC), ABX464 allows the splicing of a non-coding RNA, LncRNA 205, to produce miR-124, a potent anti-inflammatory microRNA that prevents the translation of multiple chemo- and cytokines as mentioned above. Furthermore, the replication of SARS-CoV-2 requires dynamin 2, a GTPase responsible for vesicle scission and cell penetration of the virus. Dynamin 2 is a target gene of miR-124 and downregulated by miR-124 upregulation.

Antiviral experiments were performed at the International Research Center specialized in infectiology at Claude-Bernard-Lyon-1 University, VirPath laboratory.

**Manuel Rosa-Calatrava, Ph.D., VirPath Co-director at the International Center for Infectiology Research in Lyon, France** said: *"Although in vitro results cannot predict clinical benefits in patients, this antiviral effect against SARS-CoV-2 with ABX464 obtained in our laboratory is very promising, in addition to the known anti-inflammatory properties. ABX464's antiviral effect and protection of tissue integrity are significant as they are based on a physiologic in vitro reconstituted human pulmonary epithelium model and not on the more basic monkey kidney Vero E6 cells model".*

**Philippe Pouletty, M.D., Chairman of Abivax and CEO of Truffle Capital** said*: "When we patented the anti-SARS-CoV-2 effect*

*of ABX464, based on our research on its mechanism of action and coronavirus physiopathology, we were very cautious about the ability to demonstrate an antiviral effect in such a stringent human pulmonary epithelium model. We wish to thank the VirPath team that was able to do this rapidly and rigorously."*

**Prof. Hartmut Ehrlich, M.D., CEO of Abivax** added: *"Our demonstration of the antiviral effect of ABX464 against SARS-CoV-2 further strengthens the rationale for initiating the miR-AGE clinical study, making ABX464 a promising drug candidate to be investigated clinically. With the recent approval of the miR-AGE clinical trial by ANSM (the French regulatory authorities) and the ethics committee, we will soon start patient recruitment to find out whether this triple activity of ABX464 can be translated into clinical benefits for patients diagnosed with COVID-19."*

This potential triple role of ABX464 is extremely promising, and it is the only drug candidate in the world today to show such a complementarity. In addition, convenient ABX464 daily oral dosing allows early treatment of patients in or out of hospital, to potentially act on viral replication, cytokine production, pulmonary tissue repair, before severe complications occur.

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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.

**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

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[1] Please read the press release dedicated to this announcement: "*Abivax receives ANSM and ethics committee clearance to test its development candidate ABX464 in 1,034 COVID-19 patients in randomized Phase 2b/3 clinical trial*"

[2] More than 1,000 scientific articles explain the mechanism of action of miR-124 on inflammation. ABX464 profoundly decreased the inflammation and induced clinical, biological and endoscopic remission in patients with moderate-to-severe ulcerative colitis resistant to steroids and biologic drugs, in a Phase 2a, placebo-controlled clinical trial. Currently ABX464 is evaluated in an ulcerative colitis Phase 2b clinical trial in 17 countries. It is the only drug candidate in clinical development that specifically upregulates miR-124, a physiological microRNA that down-regulates cytokine signaling and inflammation, promotes tissue repair and inhibits SARS-CoV-2 replication. TNF alpha, IL-1 beta, G-CSF, IL-6, MCP-1 and IL-17, all involved in the SARS-CoV-2 induced cytokine storm, are down-regulated by miR-124.