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

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French regulator, ANSM, as well as Ethics Committee, CPP, have cleared ABX464 for Phase 2b/3 "miR-AGE" testing

The anti-inflammatory mechanism of action could prevent and treat cytokine storm and hyper-inflammation, which lead to acute respiratory distress syndrome (ARDS) and death of COVID-19 patients

New data[1] show ABX464 inhibits SARS-CoV-2 viral replication *in vitro* in a human respiratory epithelium model, making ABX464 a molecule with a potential triple action, antiviral, anti-inflammatory and tissue repair

50 French and European clinical trial sites to treat high-risk patients with complications early

Rigorous, randomized and placebo-controlled miR-AGE trial will include 1,034 patients with convenient oral administration

Discussions being finalized with Bpifrance and SGPI for ABX464 COVID-19 project grant funding

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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 it has received clearance from France's National Agency for the Safety of Medicines (ANSM) and French Ethics Committee (CPP) to initiate a randomized, double-blind, placebo-controlled Phase 2b/3 trial of ABX464 to prevent severe inflammation that leads to acute respiratory distress syndrome (ARDS) in 1,034 COVID-19 elderly or high-risk patients (miR-AGE trial).

Oral, once-daily ABX464 has demonstrated impressive efficacy in a Phase 2a trial in another severe inflammatory disease, ulcerative colitis, and its unique molecular mechanism of action supports the rationale to treat the cytokine storm and hyper-inflammation syndrome observed in COVID-19 patients. The hyper-inflammation in the lung is the primary cause of the respiratory distress and potential death of patients. ABX464 has been shown to upregulate miR-124[2,3], a "physiological brake" of inflammation, and miR-124, a micro-RNA, 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. In addition, unlike other potent anti-inflammatories that specifically target a single cytokine, ABX464 has not been associated with increased vulnerability to opportunistic infections.

Furthermore, new breakthrough data (see Abivax second press release) show that ABX464 inhibits replication of SARS-CoV-2 (COVID-19 virus) in an *in vitro* stringent human pulmonary epithelium model, making ABX464 the

[1] See today's second press release of Abivax: "*ABX464 inhibits replication of SARS-CoV-2 (COVID-19) in reconstituted human respiratory epithelium model*"
[2] EudraCT 2020-001673-75, CPP 2020.0426 bis; 20.04.24.53420
[3] More than 1,000 scientific articles explain the mechanism of action of miR-124 on inflammation

only drug candidate with the desirable triple action to treat COVID-19 patients: anti-inflammatory, antiviral and tissue repair, thanks to its overexpression of miR-124. In addition, convenient oral dosing (one capsule per day) allows for early treatment of hospitalized as well as non-hospitalized patients.

This rigorous Phase 2b/3 trial will be performed according to high international clinical standards at 50 hospitals in France and other European countries, following the past six weeks of already completed intense preparation. The study will include robust procedures for patient selection, randomization against placebo and study monitoring as well as data collection, management, and statistical analysis.

Key elements of the trial:

- ABX464 oral dosing (50 mg once-daily) vs placebo and standard of care, 2 to 1 randomization
- 1,034 high-risk COVID-19 patients (older than 65 years or adults with risk factors)
- Enrolling hospitalized and non-hospitalized patients with confirmed SARS-CoV-2 infection, recruitment is expected to be completed within a few months
- Main evaluation criterion: absence of high-flow oxygen use or assisted ventilation or death within 28 days
- Multiple clinical and biological secondary endpoints
- Treatment (ABX464 or placebo and standard of care) duration: 28 days
- 50 French and European hospitals

This study will also address a number of crucial questions, notably ABX464's ability to prevent the acute respiratory distress syndrome (ARDS) in elderly patients with or without risk factors, in younger patients with risk factors, and secondary impacts of a SARS-CoV-2 infection on pulmonary function. In times of crisis, treatment decisions are often based on small and sometimes not correctly controlled clinical trials. This rigorously conducted study is designed in a way to provide comprehensive clinical data on the safety and efficacy of ABX464 in COVID-19 patients.

"The miR-AGE trial with ABX464 has been endorsed by renowned experts in France, Europe, and the U.S.," said **Philippe Pouletty, M.D., Chairman of the Board of Abivax and CEO of Truffle Capital**. "*Our mission is to develop drugs that improve and save patients' lives. I am proud that we can utilize Abivax's research and expertise to join the fight against the COVID-19 pandemic that affects our world*. The *COVID-19 physiopathology is complex and we must remain cautious about the potential success of the miR-AGE trial. We hope that ABX464, with its unique antiviral, anti-inflammatory and tissue repair properties and convenient oral administration, can prove to be a promising therapy for COVID-19 patients. I wish to thank our tremendous team who has been working relentlessly to launch this project, the Abivax Board of Directors and scientific advisory board, as well as the investigators, Bpifrance, ANSM and CPP for this unprecedented and collaborative effort. In parallel to the miR-AGE trial, Abivax will continue to work on its ongoing and planned clinical programs, especially the progress of the ABX464 international Phase 2b trial in ulcerative colitis.*"

Prof. Hartmut Ehrlich, M.D., CEO of Abivax, said: "*In the current situation, where there is no vaccine and no herd immunity against COVID-19, we rapidly require a treatment that will reduce the severity of this disease. Unfortunately, no prophylactic or therapeutic treatment has shown much efficacy in any rigorous trial to treat the severe form of COVID-19; helping clinicians prevent respiratory distress and death in COVID-19 patients and limit longer-term pulmonary damage is of paramount necessity. In addition, relieving hospital intensive care units of the tremendous burden that is being placed upon them is a top priority. ABX464 is an orally available small molecule that may have the potential to achieve some of these goals because of its unique mechanism and its ease of use. The robust, rigorous design of the miR-AGE ABX464 trial ensures we will draw valid scientific and medical conclusions. If the miR-AGE trial is successful, we will work with regulatory authorities to make ABX464 available as rapidly as possible. ABX464 already has demonstrated that it was safe in clinical trials to treat other inflammatory diseases. We already have ABX464 capsules in stock to treat app. 50,000 patients and could scale-up ABX464 manufacturing for over one million patients within months."*

Eric Cua, M.D., Infectiologist at the University Hospital Center (CHU) of Nice, Principal Investigator and Prof. Jean-Luc Diehl, M.D., Head of Medical ICU at Georges Pompidou European Hospital (HEGP) and Chairman of the Steering Committee for the miR-AGE trial, said: "We *fully endorse Abivax's clinical trial to assess whether early anti-inflammatory treatment with ABX464 will improve patients' outcomes. ABX464 is a late-stage development compound with a new mechanism of action, specifically, by miR-124 overexpression induced antiviral activity and down-regulation of important pro-inflammatory chemo- and cytokines like TNF alpha, IL-6, MCP-1 and IL-17, for the treatment of patients with inflammatory diseases. The molecule has already demonstrated transformational efficacy data in patients with moderate-to-severe ulcerative colitis by achieving*

clinical remissions in patients who did not improve on biologics like Adalimumab, Vedolizumab and Ustekinumab. In addition, ABX464 has shown a favorable safety profile in more than 300 volunteers and patients with HIV or ulcerative colitis. Based on these data, we believe that ABX464 should be urgently tested against placebo plus standard of care in this robust, double-blinded and sufficiently powered miR-AGE clinical trial in COVID-19 patients before they develop an acute respiratory distress syndrome."

The **CHU of Nice and its DCRI** will assist in the international coordination of the Abivax sponsored trial, and the **HEGP central laboratory** will conduct immune- and hemato-monitoring of patients.

Update on Abivax's global clinical development program: The ongoing Phase 2b clinical trial with ABX464 in ulcerative colitis remains an Abivax top priority. Given the COVID-19 crisis and related emergency situations in many hospitals, patient recruitment is now expected to be completed by the end of 2020 and first high-level results are expected in Q2 2021. The Phase 2a clinical study with ABX464 in rheumatoid arthritis should complete recruitment in 2020 with first high-level results expected in early Q1 2021. For Abivax's ongoing clinical trial with ABX196 to treat patients with hepatocellular carcinoma, the first data of the escalation phase of the study will probably be available during H1 2021.

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WEBCAST PRESENTATION

Abivax senior management will host a webcast and teleconference Thursday, May 14, 2020 at 2:00 pm CEST (Paris time), to discuss the most recent announcements and company developments, and address questions.

Attendees can participate by weblink (http://public.viavid.com/index.php?id=139890) or connect by phone using the following coordinates.

Telephone conference

Confirmation Code: 13703843

Dial in details for participants	
U.S.	877-407-0792
France	0 800 912 848
Belgium	0 800 739 04
International (all others)	1-201-689-8263

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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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ANNEX

List of opinion leaders endorsing Abivax's COVID-19 clinical trial with ABX464

- **PD Christoph Boesecke, MD**

Senior Physician, Outpatient Clinic for Infectiology & Immunology at the University Medical Center in Bonn, Germany

- **Prof. Carol L. Brosgart, MD**

Clinical Professor of Medicine, Biostatistics and Epidemiology, University of California, San Francisco (UCSF), U.S.

- **Eric Cua, MD**

Praticien Hospitalier, Infectiologist at the Infectiology Service at the University Hospital Center (CHU) in Nice, France; Investigator miR-AGE ABX464 clinical study

- **Prof. Jean-Luc Diehl**

Head of the medical ICU, Chairman of the Users' Committee, Medical mediator, INSERM UMR_S1140, Georges Pompidou European Hospital, Paris, France; Investigator miR-AGE ABX464 clinical study

- **Shahin Gharakhanian, MD**

Pharmaceutical Medicine, Infectious Diseases Principal, Shahin Gharakhanian MD Consulting LLC, Cambridge, Massachusetts, U.S.; Member of the Infectious Diseases Society of America; Member of the REACTing Covid-19 Advisory Board Fmr. Vice-President, VERTEX Pharmaceuticals, Inc, U.S., and Fmr. Attending Physician AP-HP Paris University Hospitals

- **Prof. Christoph Huber, MD**

Former Chairman, Department of Hematology-Oncology, University of Mainz and Co-Founder and Board Member of BioNTech, Mainz, Germany

- **Prof. Vincent Jarlier, MD,**

Bacteriology department, Hôpital Pitié-Salpétrière, Paris; Member of Académie de Médecine

- **Bernard Malissen, PhD**

Director of the Center for Immunophenomics, Marseille, France, and Director of the Team 'Integrative Biology of T cells and Dendritic cells' at Centre d'Immunologie de Marseille Luminy, France

- **Prof. Jürgen Rockstroh, MD**

Senior Physician, Head of Outpatient Clinic for Infectiology & Immunology at the University Medical Center in Bonn, Germany

- **Prof. Lawrence R. Stanberry, MD, PhD**

Associate Dean for International Programs, Virologist, Professor of Pediatrics Vagelos College of Physicians and Surgeons, Columbia University, New York, U.S.

- **Prof. Jamal Tazi, PhD**

Director, CNRS and Scientific Director of the Abivax – CNRS Collaborative Laboratory, Montpellier, France

- **Prof. Luc Teyton, MD, PhD**

Professor at the Scripps Research Department of Immunology and Microbiology, La Jolla, California, U.S.

- **Prof. Jacques Thèze, MD, PhD**

Member of Académie de Médecine, Former Professor of Immunology, Pasteur Institute, CEO of DIACCURATE, Paris, France