Abivax Receives French Regulatory Authority (ANSM) Approval to Include French Study Sites in its Phase 2b Ulcerative Colitis Clinical Trial and Provides a Progress Update of the ABX464 Clinical Development Plan in other Inflammatory Diseases

November 21, 2019

- **With the French Regulatory Approval by ANSM, the clinical trial is fully approved in 15 countries**
- **The clinical trial with once a day oral dosing is being conducted in 232 patients with moderate to severe ulcerative colitis in about 150 study sites**
- **As announced during UEG week (October 19-23, 2019, Barcelona, Spain), 12-month interim results of the ongoing Phase 2a maintenance study ABX464-102 confirmed the durability of safety and efficacy**
- **Patient recruitment in the Phase 2a ABX464 clinical trial in rheumatoid arthritis and preparation for Phase 2a in Crohn's disease ongoing**

PARIS--(BUSINESS WIRE)--Nov. 21, 2019-- Regulatory News:

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, announced that the French National Regulatory Authority (ANSM) has approved the ABX464-103 Phase 2b study of its lead product candidate ABX464 with once a day convenient oral dosing for treatment of patients with moderate to severe active ulcerative colitis (UC).

Prof. Dr. Hartmut J. Ehrlich M.D., Chief Executive Officer of Abivax said: *"We are very pleased with ANSM giving us the green light for the continued clinical development of this promising compound in France. As presented during UEG week in Barcelona (October 19-23, 2019), our proof of concept phase 2a studies with ABX464 in patients with moderate to severe UC showed that 75% of all evaluable patients were in clinical remission and therefore essentially free of symptoms after 2 months induction and 12 months maintenance. This remarkable percentage of clinical remissions is further strengthened by a* 78% reduction of the total mayo score, a 89% reduction of the endoscopic subscore and a 97% reduction of biomarker fecal calprotectin (normalized). *With the ABX464-103 study (Phase 2b), we are planning to confirm these excellent outcomes in a statistically relevant number of patients and, at the same time, evaluate different doses of ABX464 to define the optimal dose for subsequent Phase 3 testing. We are looking forward to advancing this exciting program with ABX464, a novel, first-in-class molecule with an innovative mode of action that could make a difference in treating patients suffering from this emaciating inflammatory disease."*

Dr. Jean-Marc Steens, Chief Medical Officer of Abivax, added: *"So far, our study results with ABX464 are truly remarkable. With currently available treatments, including biologics, typically only 10-25% of the patients achieve clinical remission after 2 months of induction, and half of the responders stop responding after six to twelve months, so there is a large unmet need for effective ulcerative colitis therapies. This is a debilitating disease that greatly affects patients' quality of life and requires expensive and cumbersome therapies. The innovative mechanism of action of ABX464 and data from this trial represent a promising new potential approach to the treatment of ulcerative colitis that could provide these patients with an easily administered, once-daily oral, long-term therapeutic management option."*

ABX464 in Ulcerative Colitis

The Phase 2b trial ABX464-103 (link to ClinicalTrial.gov) is a randomized, double-blind, placebo-controlled dose-ranging study in 232 UC patients that has have four arms: three with escalating doses of once-daily oral ABX464 (25 mg/day, 50 mg/day and 100 mg/day) and one with placebo. The study is being conducted in approximately 150 study sites in more than 15 countries under the leadership of the trial's steering committee (Prof. Séverine Vermeire, M.D., Ph.D., University Hospitals Leuven, Belgium, Prof. Herbert Tilg, M.D. Ph.D., Medical University Innsbruck, Austria, Prof. Xavier Hebuterne, M.D., Ph.D., University Hospital Nice, France, and Prof. William Sandborn, M.D., University of California San Diego School of Medicine, USA) and includes a 16-week induction phase followed by an open-label maintenance study with ABX464. The primary endpoint is reduction in modified Mayo Score at 8 weeks, and secondary endpoints will include clinical remission, endoscopic improvement and biomarker fecal calprotectin. Patient recruitment for this trial, which is conducted in cooperation with IQVIA, started in August and is proceeding according to plan. Top-line data from the induction study are expected by the end of 2020.

ABX464 in Rheumatoid Arthritis

In August 2019, the first patient was dosed in study ABX464-301 (link to ClinicalTrial.gov), a Phase 2a clinical trial of ABX464 to treat moderate to severe active rheumatoid arthritis (RA). The trial has been fully approved in four countries (France, Poland, Belgium, and Hungary). ABX464-301 is a Phase 2a study designed to evaluate the safety, tolerability and preliminary efficacy of two oral dose-levels of ABX464 administered daily, in combination with methotrexate (MTX), in 60 patients with moderate to

severe active RA who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNFα) biological therapeutics. The primary endpoint of the study will be safety and tolerability. Top-line data, after 3 months of induction treatment, are expected during the summer of 2020.

ABX464 in Crohn's disease

ABX464 will be soon investigated in a phase 2a trial in Crohn's disease, where its effects could have significant potential. The study is scheduled to initiate in Q1, 2020.

About ABX464

ABX464 was shown to exert its anti-inflammatory effects through a novel mechanism of action; it binds to the cap binding complex (CBC), which essentially sits at the 5' end of every RNA molecule in the cell. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis. Specifically, ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA, miR-124, which downregulates pro-inflammatory cytokines and chemokines like TNF-α, IL-6 and MCP-1, thereby "putting a brake" on inflammation and suggesting broad potential as a novel anti-inflammatory therapeutic agent. A seven- to ten-fold increase in miR-124 levels was observed in peripheral blood mononuclear cells (PBMCs) from healthy volunteers upon exposure to ABX464 and also in colorectal biopsies of UC patients treated with ABX464. ABX464 does not impact the splicing of cellular genes.

About ABIVAX (www.abivax.com)

ABIVAX, a clinical stage 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). More information on the company is available at www.abivax.com/en. Follow us on Twitter @ABIVAX.

DISCLAIMER

This press release contains forward-looking statements, forecasts and estimates with respect to certain of the Company's programs. Although the Company believes that its forward-looking statements, forecasts and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors that have been deemed reasonable, such forward-looking statements, forecasts and estimates are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated in such forward-looking statements, forecasts and estimates. A description 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 de Référence). 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.

This press release is for information purposes only, and the information contained herein does not constitute either an offer to sell, or the solicitation of an offer to purchase or subscribe securities of the Company in any jurisdiction, in particular in France. Similarly, it does not give and should not be treated as giving investment advice. It has no connection with the investment objectives, financial situation or specific needs of any recipient. It should not be regarded by recipients as a substitute for exercise of their own judgement. All opinions expressed herein are subject to change without notice. The distribution of this document may be restricted by law in certain jurisdictions. Persons into whose possession this document comes are required to inform themselves about and to observe any such restrictions.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191120006028/en/

Source: ABIVAX SA

Abivax
Communications
Pierre Courteille
pierre.courteille@abivax.com
+33 6 85 34 24 04

Investors
LifeSci Advisors
Chris Maggos
chris@lifesciadvisors.com
+41 79 367 6254

Press Relations and Investors Europe
MC Services AG
Anne Hennecke

anne.hennecke@mc-services.eu
+49 211 529 252 22

Public Relations France
Actifin
Ghislaine Gasparetto
ggasparetto@actifin.fr
+33 1 56 88 11 22

Public Relations France
Tilder
Marie-Virginie Klein
mv.klein@tilder.com
+33 1 44 14 99 96

Public Relations USA
Rooney Partners LLC
Marion Janic
mjanic@rooneyco.com
+1 212 223 4017