Abivax establishes clinical, regulatory and manufacturing framework for ABX464 phase 3 program and potential commercialization in 2021

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- **Pivotal ABX464 clinical trials ongoing or planned for three indications: Ulcerative colitis, Crohn's disease and Covid-19**
- **Four phase 1 studies are being initiated to generate complementary data to support the late-stage development program of ABX464**
- **Discussions planned with regulatory agencies in Europe, the US and Japan to seek recommendations and agreement with the phase 3 development approach in ulcerative colitis and Crohn's disease**
- **Development and upscaling of ABX464 manufacturing is ongoing to meet phase 3 needs and potential commercialization, in preparation of a possible positive Covid-19 trial outcome**

PARIS, December 09, 2020 – 7:45 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, announced today progression of its development program for its lead drug candidate, ABX464, into phase 3 preparation for the treatment of moderate-to-severe ulcerative colitis (UC). During 2021, Abivax will complete the induction phase of its ongoing phase 2b trial in ulcerative colitis and its ongoing phase 2b/3 study in Covid-19 patients and start the planned pivotal phase 3 program in ulcerative colitis as well as the planned pivotal phase 2b/3 study in Crohn's disease (CD).

To further support the clinical dossier from the fully enrolled ABX464 phase 2b trial in UC, with results expected in Q2 2021, three phase 1 studies in healthy volunteers are being initiated which are part of usual practice during late-stage clinical development. ABX464 has already shown a good safety profile in previous trials, these new studies will provide additional data required to support Abivax in seeking recommendations and agreement of the regulatory agencies in Europe (EMA) and the US (FDA) for the phase 3 development plan in UC, scheduled to be initiated during the second half of 2021. For the phase 1 "Thorough QT (TQT)" study, the first healthy volunteers were enrolled today. The results of this study will mitigate the need for intensive cardiac safety evaluation during the conduct of the future phase 3 trials. Further, the first participants will be enrolled in a phase 1 "Drug-Drug Interaction (DDI)" study prior to the end of 2020 to strengthen the understanding of the potential interactions of different therapeutic agents with ABX464. The third study, an "Absorption, Distribution, Metabolism and Excretion (ADME)" study, is being finalized with the objective of generating additional supporting data on the safety profile of ABX464. The three studies are expected to be completed in the course of Q3 2021.

In parallel, Abivax is evaluating its clinical study program with ABX464 in patients with ulcerative colitis in Japan. Due to specific ethnic characteristics of the Asian population, a fourth phase 1 trial is planned to confirm ABX464's pharmacokinetic profile in healthy Japanese volunteers. This step should allow inclusion of Japanese patients in the global phase 3 clinical trials in UC.

Complementing the ongoing clinical and regulatory activities, manufacturing scale-up and process optimization for development of ABX464 tablets are currently being conducted in order to add to the existing oral capsule a user-friendly tablet form. Therefore, Abivax is securing the availability of large-scale production capacities for ABX464 drug substance and drug product, working with premium industrial partners in France, Seqens and Delpharm. This will allow production of ample supplies of ABX464 for the initiation of the pivotal clinical trials in UC and CD, as well as addressing the potential commercial needs, provided that the results of the ongoing pivotal phase 2b/3 Covid-19 (miR-AGE) clinical study with ABX464 in early 2021 are positive. At present, 2021 planned ABX464 production capacities are amounting to 12 million doses.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"Abivax is establishing its clinical, regulatory and manufacturing late-stage strategies early to ensure an efficient transition of ABX464 into phase 3 clinical development and simultaneously preparing for commercialization. I am confident that the results of the ulcerative colitis phase 2b and of the complementary phase 1 studies will contribute positively to a fruitful exchange with the regulators and enable us to progress our lead drug candidate smoothly towards phase 3 and market access. As inflammatory bowel diseases, including ulcerative colitis, are also very common in parts of Asia, which have different clinical requirements, the initiation of the clinical testing of ABX464 in Japan is an important step for Abivax and will broaden partnering options. There is a worldwide high unmet medical need in inflammatory bowel diseases and, despite the promising progress for an effective Covid-19 vaccine, a potent treatment to prevent severe Covid-19 disease remains a global priority. We are putting significant efforts into ABX464 development and potential commercialization, to make ABX464 and its unique properties available to patients in need of novel treatment approaches worldwide."*

Besides the existing UC, CD and Covid-19 programs, Abivax is also taking the required steps to initiate a phase 2b clinical study in rheumatoid arthritis, provided the results of the phase 2a study, expected in Q2 2021, are positive, and pursues clinical development of its second drug candidate, ABX196, to treat hepatocarcinoma.

About Abivax (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. Follow us on Twitter @ABIVAX_.

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