Abivax Receives Clearance from U.S. FDA to Initiate Clinical Trials with ABX464 to treat Moderate to Severe Ulcerative Colitis

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- ***Active U.S. Investigational New Drug (IND) status extends Phase 2b clinical study in moderate to severe Ulcerative Colitis (UC) clinical trial to U.S. patients***
- ***ABX464 Phase 2b UC trial is already ongoing in 15 European countries and Canada***
- ***Enrollment of first U.S. patients planned for Q2, 2020***
- ***ABX464 is also in Phase 2a clinical trials to treat Rheumatoid Arthritis in Europe, and a Phase 2b clinical study in Crohn's Disease is in preparation***

PARIS, France, January 20, 2020 - 6:30 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 U.S. Food and Drug Administration (FDA) has approved an investigational new drug (IND) application for their lead drug candidate ABX464, allowing the initiation of clinical trials in the U.S. in patients with moderate-to-severe ulcerative colitis (UC). The first U.S. patients are expected to be enrolled in the ongoing Phase 2b clinical trial ABX464-103, in Q2, 2020.

Under the leadership of Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, ABX464 is currently being tested in 15 European countries and in Canada in patients with moderate-to-severe UC. This ongoing Phase 2b clinical trial (ABX464-103) in 232 patients will now be extended to the U.S. Recently published data from the Phase 2a 12 months open label maintenance study showed that 75% of the patients with moderate-to-severe active UC, who had failed on immunomodulators, anti-TNF?, vedolizumab and/or corticosteroids, were in clinical remission (meaning essentially symptom free).

In all clinical trials, ABX464 was safe and well tolerated. There were no serious adverse drug reactions reported. Adverse events were typically of mild to moderate intensity. The most common reported adverse events reported were headache, abdominal pain and diarrhea.

Prof. Hartmut J. Ehrlich, M.D., Chief Executive Officer of Abivax said: *"We are very excited about the green light from the FDA, which is a very important milestone in Abivax's global development strategy for our lead compound, ABX464. By expanding the ongoing clinical Phase 2b study of ABX464 to the U.S., Abivax is aiming to make this new potential treatment option available to a substantial number of UC patients in need of new therapeutic solutions."*

Prof. William Sandborn, M.D., Director of the Inflammatory Bowel Disease (IBD) Center at University of California (UC) San Diego Health and principal investigator of the trial, said: *"I am pleased that this promising drug candidate can now move forward with Phase 2b testing in the U.S. Based on the data from previous trials, ABX464 has the potential to address the high unmet medical need of UC patients in the U.S. and worldwide, with many of them not responding or losing responsiveness to currently available treatments."*

About ABX464
ABX464 is a highly differentiated oral drug candidate, with a novel mechanism of action based on the upregulation of a single microRNA (miRNA-124) with potent anti-inflammatory properties. ABX464 was shown to exert its anti-inflammatory effects through binding to the cap binding complex (CBC), which sits at the 5' end of every RNA molecule in the cell. By binding to the CBC, ABX464 reinforces the biological functions of CBC in cellular RNA biogenesis. Specifically, ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA, miRNA-124, which downregulates pro-inflammatory cytokines and chemokines like TNF-?, 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 miRNA-124 levels was observed in colorectal biopsies of UC patients treated with ABX464. ABX464 does not impact the splicing of cellular genes. In addition to the ongoing Phase 2b trial in UC, ABX464 is also being investigated in a Phase 2a trial in rheumatoid arthritis and soon in a Phase 2b trial in Crohn's disease, where its effects could have significant potential.

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.

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