Abivax reports excellent efficacy and safety of ABX464 in phase 2b clinical trial in ulcerative colitis and plans to proceed to phase 3

- Primary endpoint (statistically significant reduction of Modified Mayo Score[1]) was met with once-daily ABX464 (25mg, 50mg, 100mg) at week 8 in these 254 patients randomized, double-blind and placebo-controlled clinical trial

(p<0.05, intent-to-treat population [ITT])

- Key secondary endpoints, including endoscopic improvement, clinical remission, clinical response and the reduction of fecal calprotectin showed significant difference in patients dosed with ABX464 compared to placebo
- ABX464 also showed rapid efficacy in patients who were previously exposed to biologics and/or JAK inhibitors treatment

- ABX464 was safe and well tolerated
- Preliminary data from 51 patients treated with 50mg ABX464 in the open-label maintenance study showed increased and durable clinical remission and endoscopic improvement after 48 weeks[2]
- Abivax to host webcast on Tuesday May 25, 2021 at 6 pm CEST (12 pm EST, 9 am PST), with participation of Prof. Bruce Sands, M.D., M.S.

PARIS, France, May 24, 2021 – 6:30 pm (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel

therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, announces positive phase 2b clinical induction and preliminary maintenance study results. 254 patients with moderate to severe ulcerative colitis (UC) were treated with ABX464, a small molecule for once-daily administration with a first-in-class mechanism of action.

The top-line data showed significant clinical efficacy in the overall patient population on primary and key secondary endpoints and a good safety profile of ABX464 during 8 weeks of induction treatment. Importantly, the overall drop-out rate of patients in the study was only 9%, which is remarkable in view of the Covid-19 situation.

Furthermore, after 48 weeks of open-label maintenance treatment with ABX464, preliminary data from the first 51 patients showed further increased and durable clinical and endoscopic efficacy.

The phase 3 clinical program with ABX464 in UC is expected to start by year end.[3]

Abivax's clinical trial steering committee (Prof. Séverine Vermeire, Prof. William Sandborn and Prof. Bruce Sands) was convened on May 22, 2021 and reviewed and endorsed the phase 2b induction and maintenance top-line results and the corresponding conclusions.

Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, and principal investigator of the study, said: *"I am very pleased with the outcome of this clinical trial, as it confirms and extends the results from the previous phase 2a study. Clearly, this promising drug-candidate needs to be taken into phase 3 as quickly as possible, as the medical need for patients suffering from moderate to severe ulcerative colitis is very high and new safe and effective treatments with innovative modes of action are urgently needed. I am looking forward to further*

support the planned phase 3 ulcerative colitis program as principal investigator."

Prof. Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York City, NY, added[4]: *"The ABX464 phase 2b induction and preliminary maintenance results are very compelling. I am especially impressed by the efficacy in severe patients who previously failed biologic and/or JAK inhibitors treatment and by the durable and increasing efficacy during maintenance treatment. Ulcerative colitis is a chronic disease and patients need long-term effective treatments, as many of them do not respond or stop responding to currently available drugs. Beyond its efficacy, safety and differentiated mode of action, ABX464 offers a once-daily easy oral administration."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"The phase 2b results demonstrate the potential of ABX464 to become a gamechanger for the treatment of*

ulcerative colitis patients in need of new therapeutic management options. Interestingly, the lowest dose of 25mg was effective across the entire study population, including patients refractory to biologics and JAK inhibitors, with a safety profile that is very similar to the placebo group. Based on these data, we are now moving forward as quickly as possible with our phase 3 plan in ulcerative colitis as well as phase 2b/3 in Crohn's disease to bring ABX464 to the many patients suffering from inflammatory bowel disease."

Philippe Pouletty, M.D., Chairman of the Board of Abivax, commented: *"With these excellent results, Abivax enters a new and exciting execution phase towards potential market approval of ABX464 for a major unmet medical need."*

ABX464 phase 2b induction study confirmed short-term efficacy in patients refractory to conventional treatments as well as patients previously exposed to

biological and/or JAK inhibitor treatments and demonstrated a good safety profile

The randomized, double-blind and placebo-controlled phase 2b induction study was conducted at 130 study sites in 15 European countries, Canada and the US. It had three once-daily oral ABX464 treatment groups (25mg, 50mg and 100mg) and one placebo group. 254 patients with moderate to severe active ulcerative colitis were enrolled into the trial. 50% of these patients had inadequate response, loss of response, or intolerance to tumor necrosis factor alpha (TNF-α) inhibitors, vedolizumab, other biologics and/or JAK inhibitors treatments while the other 50% were refractory to conventional treatments. Endoscopies were read centrally and blinded by independent reviewers. Electronic patient diaries were used to promote the reliability of the collection of stool frequency, rectal bleedings and other patient reported outcomes.

Gender, clinical, biological and endoscopic parameters were well distributed across placebo and treatment groups at enrollment time. The primary endpoint, i.e. the reduction of the modified Mayo Score from baseline after 8 weeks of treatment was statistically significant for all active treatment groups.