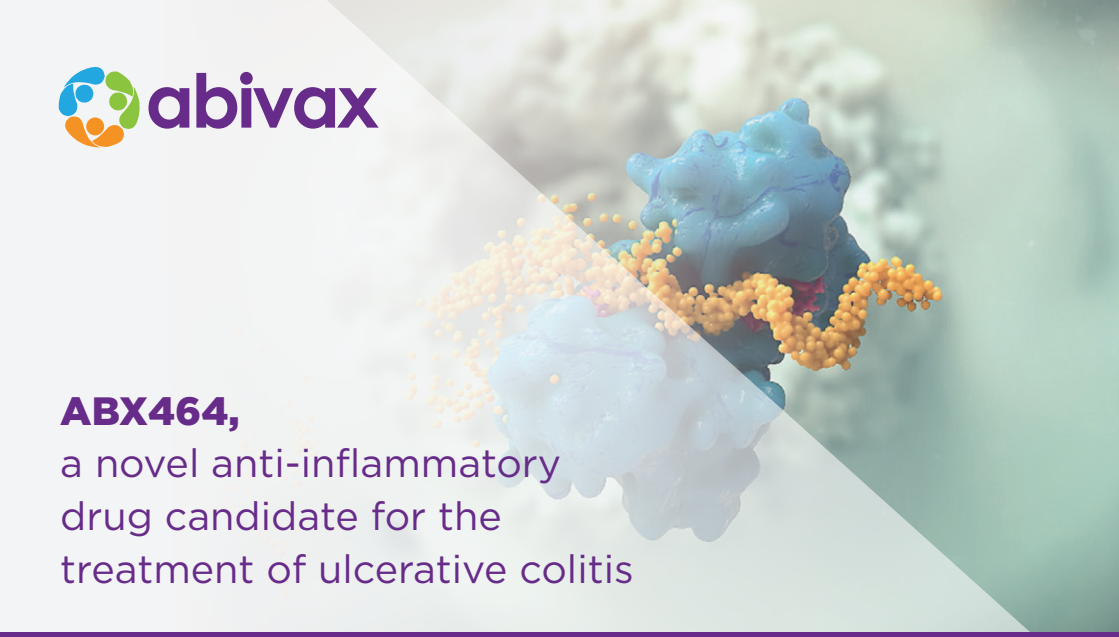

ABX464,
a novel anti-inflammatory drug candidate for the treatment of ulcerative colitis

"The ABX464 phase 2b induction and preliminary maintenance results are very compelling. I am especially impressed by the efficacy in severe patients who failed on previous treatments and by the durable and increasing efficacy during maintenance treatment. We might have in our hands a new drug with significant impact in patient care."

Prof. William Sandborn, M.D., University of California San Diego School of Medicine and Co-Founder and Chief Medical Officer at Shoreline Biosciences, CA, USA

ABOUT ABX464

ABX464 is an orally administered small molecule drug candidate which has shown a fast onset of action, durable and maintained efficacy and a good safety profile due to its unique and novel mechanism of action[1]. It is based on the upregulation of a single physiological microRNA (miR-124), a potent down-regulator of excessive inflammation.

ABX464 was shown to exert its inflammation dampening effects through binding to the cap binding complex (CBC), which sits at the 5' end of every RNA molecule in the cell. Specifically, ABX464 enhances the selective splicing of a single long non-coding RNA to generate miR-124 which downregulates key pro-inflammatory cytokines and chemokines thereby "putting a brake" on inflammation. In the phase 2b clinical study, increased miR-124 levels were observed in colorectal biopsies after 8 weeks of treatment throughout all ABX464 dose groups (25 mg, 50 mg and 100 mg). ABX464 does not impact the splicing of cellular genes.

CLINICAL STUDY RESULTS WITH ABX464 IN ULCERATIVE COLITIS

The phase 2b induction study showed a rapid onset of clinical improvements as well as efficacy in patients naïve or resistant to biologics and/or JAK inhibitor treatments.

The randomized, double-blind, and placebo-controlled phase 2b induction study had three once-daily oral ABX464 treatment groups (25 mg, 50 mg and 100 mg) 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 inhibitor treatments while the other 50 % were refractory to conventional treatments. Endoscopies were read centrally and blinded by independent reviewers. Gender, clinical, biological, and endoscopic parameters were well distributed across placebo and treatment groups at enrollment time.

The results of this study were reported in May 2021 and confirmed the results already observed in the previous phase 2a study. 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.

Primary endpoint at week 8 (ITT population / N=252)		**Placebo**	**25 mg**	**50 mg**	**100 mg**
Modified Mayo Score Mean change from baseline	All patients	-1.9	-3.1*	-3.2*	-2.9*
	Bio refractory	-1.0	-2.8*	-2.9*	-2.8*

** p-values of <0.05 versus placebo for all dose groups (ANCOVA)*

At week 8, 35 %, 40 % and 44 % of all patients treated with 25 mg, 50 mg and 100 mg respectively achieved endoscopic improvement compared to 14 % in the placebo group. It is remarkable, that, among these patients, 29 %, 30 % and 27 % (25 mg, 50 mg and 100 mg) of the most severely ill patients who were refractory to biologics and/or JAK inhibitor treatments, showed an endoscopic improvement.

Primary endpoint at week 8 (ITT population / N=252)		**Placebo**	**25 mg**	**50 mg**	**100 mg**
Endoscopic Improvement	All patients	8 (13.6%)	20 (34.5%)*	21 (39.6%)*	24 (44.4%)*
	Bio refractory	1 (3.7%)	8 (28.6%)*	7 (30.4%)*	8 (26.6%)*

**p-values of <0.05 versus placebo for all dose groups using a likelihood ratio chi-square test*

Significant clinical efficacy was also observed in the overall patient population with respect to further key secondary endpoints, such as clinical remission, clinical response and the reduction of fecal calprotectin.

These data were presented as a late-breaking abstract at the UEG Week Virtual 2021 by Prof. Séverine Vermeire, M.D., Ph.D, the principal investigator of the study, on Monday, October 4, 2021[2].

PHASE 2A AND 2B MAINTENANCE STUDY RESULTS CONFIRM PERSISTENT SAFETY AND DURABLE EFFICACY OF ABX464 IN UC PATIENTS

97.7% (217/222) of all patients who completed the phase 2b induction study, irrespective of treatments or treatment outcome during the induction phase, enrolled in the subsequent open-label maintenance study to evaluate the long-term safety and efficacy profile of ABX464 for up to two years.

Among the subset of 101 patients for whom one-year maintenance data is available (cut-off date: September 15, 2021), 28 had entered the maintenance study already in clinical remission: 23/28 (82.1%) of these patients stayed in clinical remission and only 5/28 patients (17.9%) lost clinical remission during this first year of maintenance.

Importantly, 36/73 patients (49.3%) who were not in clinical remission at the end of induction achieved a *de novo* clinical remission during the first year of maintenance.

The clinical remission rate for patients who did not show at least a clinical response at the end of the induction phase was 55.9% (PP) and 50% (ITT) after 48 weeks of treatment, demonstrating that long-term administration of ABX464 provided substantial clinical benefits also for these patients.

ABX464 is unique in inducing and maintaining clinical remission in the long-term, offering thereby a treatment that is transformative for the lives of the many patients who currently have only very limited therapeutic options for this chronic and very debilitating disease.

During the induction and the maintenance phases of the phase 2b study, ABX464 continued to show a good safety and tolerability profile, confirming the data already generated in over 1,000 patients and volunteers treated with ABX464 so far.

PREPARATIONS FOR LAUNCH OF GLOBAL PHASE 3 PROGRAM IN UC ARE ONGOING

Following the results of the phase 2a and 2b induction and maintenance trials, Abivax is preparing for the launch of a global phase 3 clinical program with ABX464 for the treatment of ulcerative colitis.

Recently, Abivax received the end-of-phase-2 response of the FDA as well as the scientific advice of the EMA. Both regulatory agencies expressed their support to move ABX464 into a pivotal phase 3 program in ulcerative colitis, with no concerns raised regarding clinical safety, non-clinical safety, or CMC. Abivax plans to enroll the first patient into this study program in Q2 2022.

References:

1) *J. Tazi et al.: Specific and selective induction of miR-124 in immune cells by the quinoline ABX464: a transformative therapy for inflammatory diseases, Drug Discovery Today, Volume 26, Issue 4, April 2021, Pages 1030–1039*

2) *UEG Week Virtual 2021: October 4, 2021: Vermeire et al.: „Oral ABX464 QD is efficacious and safe during phase 2b induction and maintenance treatment of ulcerative colitis patients"*

Thursday, **February 17,**
12:00 to 13:00

ABIVAX SATELLITE SYMPOSIUM

"ABX464, a novel anti-inflammatory drug-candidate for the treatment of ulcerative colitis"

SPEAKERS:

- **Prof. Bruce Sands M.D. (chairman),** The Dr. Burrill B. Crohn Professor of Medicine (Gastroenterology) and the Chief of the Division of Gastroenterology for the Mount Sinai Health System, NY, USA
- **Prof. William Sandborn, M.D.,** University of California San Diego School of Medicine and Co-Founder and Chief Medical Officer at Shoreline Biosciences, CA, USA
- **Didier Scherrer, Ph.D.,** Vice-President R&D at Abivax, France

This program is not affiliated with ECCO.

ABOUT ABIVAX

Abivax is a clinical stage biotechnology company developing therapies that modulate the immune system to treat inflammatory diseases, viral infections, and cancer. In 2021, Abivax published very positive results of its phase 2b induction study with ABX464 for the treatment of UC as well as preliminary data of the first 101 patients who completed the first year of maintenance treatment within this phase 2b trial. The previous phase 2a maintenance study in UC is also still ongoing, including patients who are, to date, in their fourth year of once-daily oral treatment with ABX464. Abivax recently received the end-of-phase-2 response of the FDA as well as the scientific advice of the EMA with guidance and a path forward to bring ABX464 into phase 3 clinical testing in UC.

More information on the company is available at www.abivax.com. You can also follow Abivax on LinkedIn and Twitter @ABIVAX_.

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