



Abivax publishes novel data with respect to obefazimod's anti-inflammatory mechanism of action

January 5, 2023

The scientific article in the peer-reviewed journal *Clinical and Translational Gastroenterology* describes obefazimod's capacity to selectively up-regulate a single microRNA, miR-124, leading to decreases in proinflammatory cytokines and thus acting as "a physiological brake" of inflammation and to impact the immune system *in vitro*, in murine models of inflammatory bowel disease (IBD), as well as in patients suffering from ulcerative colitis (UC)

Obefazimod is a once-daily orally administered small molecule which is currently in Phase 3 clinical trials for the treatment of UC (ABTECT program)

PARIS, France, January 5, 2023 – 08:00 a.m. (CET) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a Phase 3 clinical-stage biotechnology company focused on developing therapeutics that modulate the immune system to treat patients with chronic inflammatory diseases, today announced the publication of a scientific article in the peer-reviewed journal *Clinical and Translational Gastroenterology* (CTG) entitled: ["ABX464 \(obefazimod\) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases."](#) [1]

The publication highlights obefazimod's novel mechanism of action (MoA) and its capacity to treat patients with moderate to severe UC. The article extends the observations reported in Abivax's previous publications on the Phase 2a and Phase 2b clinical trials conducted in UC, including patients who failed to respond or stopped responding to currently available therapies.

The article reports that obefazimod has been observed to impact the immune system *in vitro*, in murine models of IBD, as well as in patients with UC. The up-regulation of a single microRNA, miR-124, *in vitro* shows that obefazimod's MoA leads to decreases in proinflammatory cytokines including IL-17 and IL-6, and in the chemokine CCL2/MCP-1, thereby potentially putting "a physiological brake" on inflammation. It reverses the expression of several inflammatory cytokines without impairing host defense as it does not impact the immune response altogether. These scientific findings may explain its short- and long-term efficacy along with a favorable tolerability and safety profile which were observed during the clinical Phase 2a and Phase 2b induction and maintenance clinical trials conducted in UC patients.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: "Abivax feels very encouraged by the data published in our article and the validation and extension of obefazimod's novel and potent anti-inflammatory mechanism of action. The data complement our scientific findings released on our clinical Phase 2a and Phase 2b induction and maintenance results which were generated with obefazimod for the treatment of patients with moderate to severe ulcerative colitis. The article once again supports the rationale that our lead molecule has the potential to efficiently, durably and safely treat UC patients. This specific MoA acts through the upregulation of a specific anti-inflammatory microRNA which reduces the expression of several pro-inflammatory cytokines. Consequently, the excessive immune response leading to the chronic inflammation of the bowel may be balanced through a continued treatment with obefazimod. We believe that obefazimod has the potential to also become an effective long-term therapy for other chronic inflammatory diseases with high medical need."

About obefazimod

Abivax believes obefazimod is a highly differentiated oral drug candidate, with a novel mechanism of action based on the upregulation of a single microRNA (miR-124) with potent anti-inflammatory properties. Obefazimod 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, obefazimod reinforces the biological functions of CBC in cellular RNA biogenesis. Specifically, obefazimod enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA, miR-124, which downregulates the translation of pro-inflammatory cytokines and chemokines like TNF- α , IL-6, CCL2/MCP-1 and IL-17, as well as Th17+ cells. This downregulation thereby potentially "puts a brake" on inflammation and suggests broad potential as a novel anti-inflammatory therapeutic agent. Laboratory analysis of the Phase 2b trial in UC at week eight showed a highly statistically significant upregulation of miR-124 in rectal tissue in all patients treated with obefazimod, compared to baseline. The median increases were 13-fold for the 25 mg group, 25-fold for the 50 mg group and 25-fold for the 100 mg group, while no upregulation was observed in the placebo group (1.02-fold increase), indicative of the positive pharmacological effect of obefazimod. Importantly, obefazimod does not impact the splicing of cellular genes.

Obefazimod for the treatment of adults with moderate to severe ulcerative colitis

Obefazimod is currently in Phase 3 clinical trials for the treatment of ulcerative colitis ("ABTECT program") with the first patient enrolled in the United States on October 11, 2022.

1,200 UC patients across 36 countries will take part in the pivotal Phase 3 program that consists of two induction trials (ABTECT-1 (ABX464-105) and ABTECT-2 (ABX464-106)) and a single subsequent maintenance trial (ABX464-107).

The ABTECT program aims to confirm obefazimod's potential to maintain and further improve patient-outcomes over time, as well as its favorable safety and tolerability profile, as already observed during previously conducted Phase 2a and Phase 2b clinical trials in moderate to severe UC.

About Abivax (www.abivax.com)

Abivax is a Phase 3 clinical stage biotechnology company, focused on developing therapeutics that modulate the immune system to treat patients with chronic inflammatory diseases. Abivax, founded by Truffle Capital, is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of ulcerative colitis. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

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[1] Apolit et al.: [ABX464 \(obefazimod\) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases](#), CTG, published online Jan. 2023.