Abivax: Publication of an expert article in JCC on obefazimod as promising therapeutic management option for UC patients

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The authors of the expert article published in the *Journal of Crohn's and Colitis* include major European and North American Key Opinion Leaders in the field of Inflammatory Bowel Diseases

The KOLs state that obefazimod is a first-in-class drug with a unique mechanism of action and with great promise in the therapeutic management of ulcerative colitis patients

The experts expect that the results from the ongoing Phase 3 program with obefazimod in UC will confirm its potential to rapidly and durably relieve patients from their symptoms

PARIS, France, May 2nd, 2023 – 06:00 p.m. (CEST) – 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 announces the *Journal of Crohn's and Colitis (JCC)* publication of a piece titled "*Obefazimod: a first-in-class drug for the treatment of ulcerative colitis*"[1], written by global Inflammatory Bowel Disease (IBD) experts.

The authors of the publication include major European and North American Key Opinion Leaders (KOLs) in the field of IBD, e.g. Séverine Vermeire (Belgium), Virginia Solitano (Italy and Canada), Laurent Peyrin-Biroulet (France), Herbert Tilg (Austria), Silvio Danese (Italy), and Bruce Sands (United States).

The KOLs conclude, obefazimod is a first-in-class drug with a unique mechanism of action that holds great promise in the therapeutic management of ulcerative colitis (UC) patients. The experts further expect the results from the ongoing Phase 3 program with obefazimod for the treatment of UC (ABTECT program) will confirm the previous outcomes and their conclusions issued in this publication.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said. *"We are proud of the publication of this expert opinion written by internationally leading KOLs in the field of IBD. The conclusion that obefazimod holds great promise as a novel therapeutic management option for UC patients is very motivating for the Abivax team. We believe we are on the right track to confirm our lead drug candidate's ability to swiftly and durably relieve UC patients from their symptoms. We are encouraged by the leading KOLs, as well as our investors and partners shared view about the potential of obefazimod and also by the increased interest of the scientific, medical and investment community in our molecule. We are determined to conclude our ongoing Phase 3 program as quickly as possible and make obefazimod available to all UC patients, especially to those who urgently need alternative treatment options."*

Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, and principal investigator of the ABTECT program in Europe, adds: *"Our expert analysis took into account all the different aspects of the preclinical and clinical development of obefazimod, including the most recent insights on its unique mechanism of action. We came to the conclusion that obefazimod might change the treatment paradigm of ulcerative colitis and inflammatory bowel diseases in the future. We continue to be impressed by its clinical efficacy, especially in the course of the maintenance treatment as well as by its safety profile. Therefore, we are very interested in completing the Phase 3 program of obefazimod in UC which we believe can confirm the outcomes of the Phase 2a and Phase 2b trials. We urgently need potent and long-term efficient treatments that are well tolerated by the patients and, with obefazimod, we might have such a candidate in our hands."*

The article analyses the results generated in preclinical studies as well as clinical trials conducted with obefazimod in ulcerative colitis, rheumatoid arthritis, Covid-19 and HIV patients. The KOL's analysis is summarized in the following main conclusions:

- Obefazimod enhances the selective splicing of a single long non-coding RNA to generate an anti-inflammatory microRNA called miR-124. miR-124 is responsible for downregulation of key pro-inflammatory cytokines and chemokines thus exerting its inflammation dampening effects. The sustained overexpression of miR-124 might explain why obefazimod provides a high remission rate in UC patients after one and two years of continued daily dosing. In parallel, miR-124 does not only decrease mucosal inflammation, but it also promotes tissue repair.
- Evidence from Phase 2 clinical trials supports the anti-inflammatory effect of obefazimod. Findings from the maintenance phases of the trials showed that the long-term treatment with the molecule provides continued improvement in clinical symptoms of the disease, with a substantial proportion of patients in clinical remission.
- All clinical studies of obefazimod have shown a consistent and good safety profile, during the induction as well as in the subsequent maintenance trials. The most common treatment-emergent adverse events (TEAEs) were headache and nausea. Headaches occurred early during the first 10 days of treatment, were generally mild to moderate and lasted only a few days. There was no signal of serious infection or malignancies.
- Obefazimod exerted no effect on the immune system in the absence of inflammation, therefore supporting a mechanism of action as modulator of immune cell activation during inflammation but not in its absence. These findings provide evidence that upregulating miR-124 by obefazimod reverses the expression of several pro-inflammatory cytokines triggered during inflammation but does not blunt the immune response altogether.

In order to confirm the fast onset of action, the long-term efficacy results as well as the safety profile that obefazimod generated notably in its Phase 2a and Phase 2b clinical trials for the treatment of UC patients, Abivax is currently conducting an international Phase 3 clinical program (ABTECT).

1,200 patients suffering from moderate to severe UC at 600 investigator sites covering North America, Europe, Latin America and Asia Pacific will be included in the two induction trials (ABTECT-1 and ABTECT-2) followed by a single maintenance trial to confirm obefazimod's fast onset of action and its long-term efficacy.

Top-line results of the two induction trials are expected to become available by the end of 2024. The results of the single maintenance trial are

expected by the end of 2025.

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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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DISCLAIMER

[1] Vermeire et al.: Obefazimod: a first-in-class drug for the treatment of ulcerative colitis, JCC, published online in May 2023 (DOI: 10.1093/ecco-jcc/jjad067).