Abivax: first US patient enrolled in global phase 3 program with obefazimod in ulcerative colitis

October 11, 2022

First patient enrolled into the global phase 3 program with obefazimod ("ABTECT-Program") for the treatment of moderate to severe ulcerative colitis (UC) in the US

1,200 UC patients across 36 countries and 600 study centers will take part in the ABTECT program which consists of two induction studies and a single subsequent maintenance study

Obefazimod 25mg and 50mg doses will be investigated in advanced therapies naïve and in advanced therapies failure patients

Program is progressing according to plan and top-line results of the two induction studies are expected to become available end of 2024

PARIS, France, October 11, 2022 – 06:00 p.m. (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a phase 3 clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, announces today that the first patient has been enrolled in the US into its global phase 3 clinical program ("ABTECT program" [1]) with product candidate obefazimod for the treatment of moderate to severe ulcerative colitis (UC).

Prof. Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai Chief of the Henry D. Janowitz Division of Gastroenterology at Mount Sinai, New York, NY, and principal investigator of the studies in the US, said[2]: *"As the principal investigator in the US, I am excited about the first patient included in the obefazimod phase 3 program for the treatment of moderate to severe UC. US investigators are highly motivated to recruit patients into the two initial induction studies. Obefazimod has already shown very promising results in the precedent phase 2a and phase 2b induction and maintenance trials. As a practicing gastroenterologist, I am confronted every day with the high unmet medical need for safe therapies that have long-term efficacy and convenient administration for patients with ulcerative colitis. I am optimistic that the ABTECT program will confirm obefazimod's potential to address these medical needs."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, added: *"We are very happy that our pivotal global phase 3 program has successfully started in the US with the enrollment of the first patient. Our focus is now to timely complete the recruitment of UC patients into the two induction studies for which the top-line results are expected for the end of 2024. Given our previous experience, we expect a vast majority of the patients completing the induction trials to enroll into the subsequent maintenance study and to reproduce the outstanding long-term phase 2a and 2b safety and efficacy results with obefazimod. Once the required data are available, we will proceed swiftly to request market authorizations in the US and in Europe, also supported by the unique mechanism of action of obefazimod and its easy, once-daily oral administration. The entire Abivax team stays committed to make obefazimod rapidly available to all the UC patients in need."*

The phase 3 program aims to confirm the excellent results from its phase 2b open-label maintenance study reported in April 2022, including the full set of 217 patients who completed one year of once-daily oral treatment with 50mg obefazimod or who dropped out of the study. These results emphasized obefazimod's capacity to maintain and further improve patient-outcomes over time, as well as its continued favorable safety and tolerability.

The phase 2b induction trial and 48-week extension results of obefazimod in UC have recently been scientifically validated and published as an article in the peer-reviewed journal "The Lancet Gastroenterology & Hepatology". [3],[4]

About the obefazimod global pivotal phase 3 clinical program in UC ("ABTECT program")

1,200 UC patients across 36 countries will take part in the pivotal phase 3 program that consists of two induction studies and a single subsequent maintenance study (ABTECT-1 (ABX464-105) and ABTECT-2 (ABX464-106) induction trials and ABTECT maintenance trial (ABX464-107)). These three pivotal studies are all randomized, double-blind, and placebo controlled, using independent, blinded review of the videotaped endoscopies. The primary efficacy endpoint, assessed at week 8 in the induction and at week 44 in the maintenance study, will be clinical remission according to the modified Mayo Score, as required by FDA.[5]

In consultation with international regulators, including both the FDA and EMA, obefazimod 25mg and 50mg will be investigated in the ABTECT program for the treatment of UC in advanced therapies (AT) naïve and in AT-failure patients[6] to support the future submission of marketing authorizations.

Abivax is working with IQVIA, a global premier CRO, to jointly set-up and conduct these studies in Europe, the Americas, Japan and other global geographies.

Thus far, more than 460 study sites, out of the targeted 600 sites, have been qualified to take part in the phase 3 trials. 137 sites (25%) will be located in North America, 234 sites (42%) will be initiated in Europe, 146 sites (26%) in Asia and 39 sites will be situated in other geographies (7%).

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About Abivax (www.abivax.com)

Abivax, a phase 3 clinical stage biotechnology company, is developing novel therapies that modulate the body's natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax, founded by Truffle Capital, is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, obefazimod (ABX464) to treat severe inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

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[1] **AB**X464 **T**reatment **E**valuation for ulcerative **C**olitis **T**herapy (ABTECT) program

[2] Dr. Bruce Sands is a paid consultant for Abivax and a member of the Steering Committee for the phase 3 program. He has not been compensated for any media work.

[3] Severine Vermeire et al.: ABX464 (obefazimod) for moderate-to-severe, active ulcerative colitis: a phase 2b, double-blind, randomised, placebo-controlled induction trial and 48-week, open-label extension, Lancet Gastroenterol Hepatol, published online on Sept. 5, 2022.

[4] The extension efficacy set in the publication includes 78 patients who either completed 48 weeks (73 patients) or were scheduled to complete 48 weeks (5 patients had discontinued).

[5] Modified Mayo Score refers to stool frequency, rectal bleeding and endoscopy sub score.

[6] Advanced therapies include biologics (TNF inhibitors, anti-integrins, anti-IL-23), and/or S1P receptor modulators, and/or JAK inhibitors.