Abivax reports two-year efficacy and safety data of obefazimod phase 2b maintenance trial in ulcerative colitis

April 17, 2023

The analysis demonstrates clinical remission in 52.5% (n=114) of 217 moderate to severe ulcerative colitis (UC) patients (intent-to-treat population, ITT) after two years (96 weeks) of once-daily oral 50mg obefazimod

In the subgroup of patients who did not achieve a clinical remission after the 8-week induction study, 48.2% of the patients (n=81) achieved a *de novo* clinical remission after two years

Endoscopic improvement and endoscopic remission at two years were achieved by 59.0% (n=128) and 35.9% (n=78) of the patients respectively

The safety and tolerability profile observed was consistent with previous findings and no safety signals were observed

PARIS, France, April 17, 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 reports the results from the final analysis of its Phase 2b open-label maintenance study, including 164 patients who completed the second year of once-daily oral treatment with 50mg obefazimod. These data emphasize obefazimod's potential to maintain and further improve patient outcomes over time, as well as its safety and tolerability profile suitable for chronic use.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"These two-year maintenance results are a strong confirmation of obefazimod's potential to swiftly induce and, more importantly, maintain long-term efficacy in patients with moderate to severe ulcerative colitis.",* **and Sheldon Sloan, M.D., M. Bioethics, CMO of Abivax, added:** *"Patients suffering from chronic inflammatory diseases, such as UC, often struggle to find a long-term effective treatment. The existing high unmet medical need results from the significant proportion of UC patients who stop responding to currently available therapies within the first year of treatment, or who do not respond at all. Therefore, at Abivax, we want to make our drug-candidate obefazimod available as quickly as possible to patients suffering from ulcerative colitis and we believe that it has the potential to make a real difference to control the disease in the long run."*

Prof. Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System, New York, NY, and principal investigator of the trials in the US, commented: *"I am excited about the two-year efficacy results of the Phase 2b trial of obefazimod in patients suffering from moderate to severe UC. The rates of maintained efficacy observed at 96 weeks are excellent. Moreover, obefazimod also continues to show excellent safety and is well-tolerated by patients, which is important for its chronic, once-daily use. I am optimistic that the ongoing Phase 3 program with obefazimod in UC will confirm these very encouraging data. Patients, as well as gastroenterologists, are in need of a medication that is efficacious over a long period of time, safe and well-tolerated, and easy to administer at the same time."*

(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.)

Obefazimod Phase 2b clinical maintenance trial results in ulcerative colitis

97.7% (n=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 open-label maintenance study to evaluate the long-term safety and efficacy profile of obefazimod for up to two years.

The final analysis after two years of treatment from the Phase 2b open-label extension study in UC included the intent-to-treat population (ITT) of 217 patients who enrolled into the maintenance study with 50mg obefazimod once-daily oral:

Results at week 96*	**ITT after 96 weeks n=217** (Non-responder imputation)
Clinical remission[1]	52.5% (n=114)
Endoscopic improvement[2]	59.0% (n=128)
Endoscopic remission[3]	35.9% (n=78)
Clinical response[4]	70.5% (n=153)

* Drop outs were considered as treatment failures in the ITT analysis (30 patients dropped out during the first year; 6 patients did not qualify for the second year of treatment due to non-response after the first year and 17 patients dropped out during the second year).

Among the 217 patients who continued their treatment with 50mg once-daily oral obefazimod, 49 were already in clinical remission after the 8-week induction trial. 67.3% (n=33) out of these 49 patients stayed in clinical remission during the maintenance treatment. Further, out of the 168 patients who were not in clinical remission at the end of the induction phase, 48.2% (n=81) showed a *de novo* clinical remission at the end of the two-year maintenance therapy with obefazimod.

Furthermore, the clinical remission rate for patients who did not show at least a clinical response at the end of the 8-week induction phase was 43.0% (n=40) after two years of treatment, demonstrating that long-term administration of obefazimod provided substantial clinical benefits also for these patients.

75% (n=164/217) of the patients included in the maintenance trial completed two years of once-daily oral dosing with 50mg obefazimod. 30 patients dropped out during the first year of treatment. 6 patients did not qualify for the second year due to non-response after the first year of treatment, and 17 patients dropped out during the second year. These patients were all considered as treatment failures in the ITT analysis.

During the induction and the maintenance treatments of the Phase 2b trial, the safety and tolerability profile observed was consistent with previous findings and no safety signals were observed.

254 patients with moderate to severe active ulcerative colitis were enrolled into the phase 2b clinical study and dosed within three once-daily oral obefazimod treatment groups (25mg, 50mg and 100mg) or placebo. 50% of these patients had inadequate response, loss of response, or intolerance to biologics and/or JAK inhibitor treatments while the other 50% were refractory to conventional treatments. Endoscopies were read centrally and blinded by independent reviewers. The baseline disease characteristics were well balanced across all obefazimod dose groups and the placebo group. Enrolled patients suffered from longstanding UC with an overall mean disease duration of 8.05 years and 71.4% of the patients had a severe disease profile (baseline modified Mayo Score of 7 to 9 points).

As of November 2022 (last safety data cut-off), 1,074 patients and volunteers were treated with obefazimod, of which 209 patients have been treated with 50mg obefazimod for one year or more. To date, no signal of opportunistic infections or malignancies have been detected.

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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] Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.

[2] Endoscopic improvement is defined as endoscopic subscore ≤1.

[3] Endoscopic remission is defined as endoscopic subscore = 0.

[4] Clinical response (per Modified Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥2 points and ≥30% from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1.