Abivax phase 2b study results of obefazimod (ABX464) in ulcerative colitis published in the Lancet Gastroenterology & Hepatology

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Phase 2b induction trial and 48-week extension results of obefazimod in ulcerative colitis (UC) published in the prestigious, peer-reviewed journal “The Lancet Gastroenterology & Hepatology”

Scientific community validates the capacity of obefazimod to rapidly and durably relieve the symptoms of patients suffering from moderate to severe longstanding UC

Initiation of the global phase 3 clinical program with obefazimod in UC progresses according to plan and “First-Patient-In” is scheduled for end of September 2022

PARIS, France, September 6, 2022 – 08:00 a.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 a scientific article has been published in the peer-reviewed journal “The Lancet Gastroenterology & Hepatology”, the world-leading gastroenterology and hepatology research journal.[1] The title of the article is *“ABX464 (obefazimod) for moderate to severe active ulcerative colitis: a randomised, placebo controlled phase 2b induction trial and 48-week extension”* ***[2]***.

The publication highlights that all doses of obefazimod tested during the induction study (25mg, 50mg and 100mg) significantly improved the condition of patients suffering from moderate to severe, active ulcerative colitis compared to placebo, as measured by changes in Modified Mayo Score[3] from baseline at week 8. Further, the data show that patients on continuous daily treatment with 50mg obefazimod during the 48 weeks maintenance trial experienced new or maintained clinical response, clinical remission, endoscopic improvement and endoscopic remission.[4]

Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, and principal investigator of the study, said: *“As principal investigator, I am pleased that these very promising results of the phase 2b induction and 48-week maintenance study have been published in the renowned journal The Lancet Gastroenterology & Hepatology. This validates the safety and efficacy data generated with obefazimod in the initial phase 2a study in patients suffering from ulcerative colitis, including in a patient population refractory to biologics and/or JAK inhibitor treatments. I am impatient to start the global phase 3 program in UC and confident that we can confirm the rapid onset of action and maintained efficacy of obefazimod along with its good safety profile.”*

Prof. Bruce Sands, M.D., M.S., the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York City, NY, added[5]:*“The data generated so far with obefazimod in the phase 2a and phase 2b induction and maintenance studies gives reason to believe that this drug candidate may change the treatment paradigm for bio-naïve as well as refractory ulcerative colitis patients. The maintained efficacy signal and the good tolerability profile differentiate obefazimod from many other products on the market or in late-stage testing in UC. Further, it offers an easy once-daily oral administration. I am glad to be the lead investigator in the US for the phase 3 testing of this promising molecule.”*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, commented: *“This publication of obefazimod phase 2b induction and maintenance data in moderate to severe ulcerative colitis patients in the Lancet Gastroenterology & Hepatologyis a great achievement for Abivax. This is very meaningful recognition by the scientific community that obefazimod has the potential to become a safe and effective chronic treatment for UC patients, relieving symptoms and improving quality of life in the long run. Abivax’s current priority is the swift start and completion of the global phase 3 program in order to support NDA and MAA review by regulatory agencies to allow obefazimod approval and availability to UC patients in need of innovative, alternative therapeutic options.”*

254 patients with moderate to severe active ulcerative colitis were enrolled into the phase 2b clinical study and dosed with obefazimod within three once-daily oral 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 dose groups of obefazimod 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 showed a severe disease profile (baseline modified Mayo Score of 7 to 9 points).

At week 8 of the induction study, the primary endpoint (statistically significant reduction of Modified Mayo Score) was met with once-daily administration of obefazimod (25mg, 50mg, 100mg).

Further, all key secondary endpoints, including endoscopic improvement, clinical remission, clinical response and the reduction of fecal calprotectin showed significant difference in patients dosed with obefazimod compared to placebo. Importantly, obefazimod also showed rapid efficacy in patients who were previously exposed to biologics and/or JAK inhibitors treatment.

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

Out of these 217 patients, the 48-week data of the first 78 patients were available at the time of manuscript preparation.

Meanwhile, Abivax confirmed the data of these first 78 maintenance patients and reported excellent results from the entire cohort of its phase 2b open-label maintenance study in April this year. This interim analysis after one year once-daily treatment with 50mg obefazimod included all 217 patients who enrolled into the maintenance study and the data emphasizes the capacity of obefazimod to maintain and further improve patient outcomes over time, as well as its continued favorable safety and tolerability.

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

Global pivotal phase 3 clinical program with obefazimod in ulcerative colitis

The initiation of the global phase 3 clinical program with obefazimod for the treatment of moderate to severe UC is on track and the “First-Patient-In” is scheduled for end of September 2022.

In consultation with international regulators, including the US and European regulatory agencies (FDA and EMA), 25mg and 50mg will be investigated in phase 3 for both induction and subsequent maintenance in UC.

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

Currently, more than 430 study sites, out of the targeted 600 sites, have already been qualified for the phase 3 trials.

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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 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_.

Contacts

Abivax
Communications
Regina Jehle
regina.jehle@abivax.com
+33 6 24 50 69 63

Investors
LifeSci Advisors
Ligia Vela-Reid
lvela-reid@lifesciadvisors.com
+44 7413 825310

Press Relations & Investors Europe
MC Services AG
Anne Hennecke
anne.hennecke@mc-services.eu
+49 211 529 252 22

Public Relations France
Actifin
Ghislaine Gasparetto
ggasparetto@actifin.fr
+33 6 21 10 49 24

Public Relations France
Primatice
Thomas Roborel de Climens
thomasdeclimens@primatice.com
+33 6 78 12 97 95

Public Relations USA
Rooney Partners LLC
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646 770 8858

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[1] "The Lancet Gastroenterology & Hepatology" has an Impact Factor of 45 (2021 Journal Citation Reports ®, Clarivate 2022).

[2] 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, Severine Vermeire et al., Lancet Gastroenterol Hepatol, published online on Sept. 5, 2022 (https://doi.org/10.1016/S2468-1253(22)00233-3).

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

[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] Dr. Bruce Sands is a paid consultant for Abivax. He has not been compensated for any media work.