Abivax abstract on obefazimod phase 2b results selected for moderated poster presentation at UEG Week 2022

September 27, 2022

Obefazimod (ABX464) interim 48-week safety and efficacy analysis from the ongoing phase 2b maintenance study in moderate-to-severe ulcerative colitis (UC) selected by UEG as "one of the best abstracts" and eligible for an oral presentation at a moderated poster session

Principal investigator Prof. Séverine Vermeire, M.D., Ph.D., to present Abivax's poster on October 10, 2022, at 11:54 a.m.- 12:00 (noon) CEST (5:54 a.m.-6:00 a.m. EST)

PARIS, France, September 27, 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 its abstract on the obefazimod interim 48-week safety and efficacy analysis from the ongoing open-label phase 2b maintenance study in moderate to severe ulcerative colitis (UC) has been selected as "one of the best abstracts" for UEG (United European Gastroenterology) Week 2022. The corresponding poster is therefore eligible for an oral presentation during a moderated poster session, in addition to the poster exhibition in the Science Lounge and the Virtual Poster Exhibition.

UEG Week 2022 takes place in Vienna, Austria, from October 8-11, 2022, and is one of the world's leading congresses focused on gastrointestinal diseases, such as Inflammatory Bowel Diseases (IBD).

The poster will be presented by Prof. Séverine Vermeire, M.D., Ph.D., the study's principal investigator. Participants will have the opportunity to ask questions after the presentation.

Abstract:	#AS-UEG-2022-01013
Session:	Clinical trials in IBD – Moderated Poster Session 3 (MP250)
Talk:	ABX464 (obefazimod) in patients with moderate-to-severe ulcerative colitis: An interim 48-week safety and efficacy analysis from an ongoing 96-week open-label maintenance phase 2b study
Time:	October 10, 2022 – at 11:54 a.m.-12:00 (noon) CEST (5:54-6:00 a.m. EST)
Presenter:	Prof. Séverine Vermeire, M.D., Ph.D., Head of the IBD Center at the University Hospitals Leuven, Belgium, and principal investigator of the obefazimod phase 2a and phase 2b clinical studies, as well as of the obefazimod global phase 3 clinical program in UC

The moderated poster sessions at this year's UEG Week will neither be recorded nor streamed online. Only registered UEG Week participants can attend the poster session at the conference venue.

In addition to the selection of the abstract by UEG, the obefazimod phase 2b study results in UC have recently been scientifically validated with the publication of an article in the peer-reviewed journal "The Lancet Gastroenterology & Hepatology". [1] The title of the article is "*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*". [2]

Obefazimod global pivotal phase 3 clinical program in UC

Following the promising results of the phase 2a and phase 2b clinical induction and maintenance studies with obefazimod in UC, Abivax launched a global pivotal phase 3 clinical program with its drug candidate in moderate to severe ulcerative colitis patients.

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 (induction) and at week 44 (maintenance) will be clinical remission according to the modified Mayo Score, as required by FDA.[3]

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

In August, Abivax received approval from the central US Institutional Review Board (IRB) for the protocols of the phase 3 induction studies. This allows the initiation of enrollment of patients into the two studies in UC in the US. A first patient is anticipated to be included at the end of September 2022.

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

[2] 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.

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