Abivax phase 3 program with obefazimod in ulcerative colitis progresses with US IRB approval

August 4, 2022

Phase 3 clinical induction study protocols for obefazimod in ulcerative colitis (UC) are approved by central US IRB (Institutional Review Board)

Start-up activities are on track and FPI (First-Patient-In) expected in the US by end Q3 2022

First submissions of the phase 3 study protocols to European regulatory agencies planned in August 2022

PARIS, France, August 4, 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, 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 phase 3 induction studies with lead drug candidate obefazimod (ABX464) in UC in the US. A First-Patient-In (FPI) is anticipated for end Q3 2022.

Following the End-of-Phase-2 meeting with US regulatory agency, FDA, and scientific advice with the European regulatory agency, EMA, in late 2021, Abivax has submitted final phase 3 protocols and the required supportive information to the US IND in June 2022.

In Europe, the clinical trial applications for the phase 3 protocols will be submitted under the new Clinical Trial Regulation in August 2022 and approval is expected by December 2022.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"We are very pleased with the US IRB approval of the phase 3 induction protocols to confirm efficacy and safety of obefazimod in adults with moderate to severe ulcerative colitis. Enrolment of patients can be initiated for the two induction studies and subsequently for the maintenance trial. Patients and caregivers urgently need alternative therapeutic options for the treatment of ulcerative colitis. The obefazimod phase 2b study provides compelling long-term efficacy data demonstrating potential for obefazimod to substantially and durably improve the lives of UC patients in the US and worldwide. Abivax is confident that the phase 3 studies will confirm the positive and promising results of the phase 2a and 2b induction and maintenance trials.[1]"*

And Didier Blondel, CFO of Abivax, added: *"We are pursuing several options for extending our cash runway beyond end of September 2022, taking into account the current fundraising environment for biotech companies. The whole Abivax team is looking forward to the inclusion of the first patient in the phase 3 studies."*

Global phase 3 clinical program with obefazimod in ulcerative colitis

1,200 moderate to severe UC patients across 36 countries will take part in the pivotal phase 3 program which consists of two induction studies and a subsequent maintenance study (*ABTECT-1 and ABTECT-2 induction trials - ABX464-105 and ABX464-106 - and ABTECT maintenance trial - ABX464-107*). These three pivotal studies are all randomized, double-blind and placebo controlled, using independent and central review of the video-taped 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[2] as required by FDA. Abivax plans to post the trial designs as well as participating study sites on clinicaltrials.gov by end of September.

In consultation with international regulators, including FDA and EMA, obefazimod 25mg and 50mg will be investigated in phase 3 for the treatment of UC in advanced therapies (AT) naïve and in AT-failure patients[3] 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 across 36 countries in Europe, the Americas, Japan and other global geographies.

Currently, more than 400 study sites, out of the targeted 600 sites, have already been qualified to take part in 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_.

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[1] Obefazimod (ABX464) phase 2a clinical induction and maintenance studies (NCT03093259 and NCT03368118) and obefazimod (ABX464) phase 2b clinical induction and maintenance studies (NCT03760003 and NCT04023396). The phase 2a and phase 2b maintenance studies have now been merged into one single maintenance trial (NCT05177835).

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

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