Abivax receives FDA agreement on pediatric development plan with obefazimod in IBD

December 20, 2022

The FDA agreed on the initial Pediatric Study Plan (iPSP) for the development of obefazimod in children aged 2 to 17 years with inflammatory bowel diseases (IBD)

Abivax global Phase 3 clinical program (ABTECT program) with obefazimod for the treatment of ulcerative colitis (UC) is ongoing with the first patient enrolled in the US on October 11, 2022

PARIS, France, December 20, 2022 – 06:00 p.m. (CET) – 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 announced that the US Food and Drug Administration (the FDA) provided their agreement on the initial Pediatric Study Plan (iPSP) for the development of obefazimod in ulcerative colitis in children from 2 to 17 years old.

Following completion of End of Phase 2 Meeting, Abivax initiated a Phase 3 program (ABTECT program) with obefazimod in adults with moderate to severe ulcerative colitis, which includes patients aged 16 and over. Recognizing the impact of IBD in children and adolescents, Abivax is further committed to the pediatric development of obefazimod, starting with ulcerative colitis.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said: *"The FDA agreement on the pediatric plan for obefazimod in IBD is an important step for Abivax to establish a wholistic and comprehensive development plan that includes an adult patient population as well as children and adolescents suffering from these diseases. Ulcerative colitis or Crohn's disease often occur at a young age and may have a heavy impact on the quality of life and also on the general health and wellbeing of children and teenagers. With obefazimod, Abivax is committed to developing an efficient treatment option for these younger patients."*

Obefazimod for the treatment of adults with moderate to severe ulcerative colitis

Obefazimod is currently in Phase 3 clinical trials for the treatment of ulcerative colitis ("ABTECT program") with the first patient enrolled in the United States on October 11, 2022.

1,200 UC patients across 36 countries will take part in the pivotal Phase 3 program that consists of two induction trials (ABTECT-1 (ABX464-105) and ABTECT-2 (ABX464-106)) and a single subsequent maintenance trial (ABX464-107).

The ABTECT program aims to confirm obefazimod's potential to maintain and further improve patient-outcomes over time, as well as its favorable safety and tolerability profile, as already observed during previously conducted Phase 2a and Phase 2b clinical trials in moderate to severe UC.

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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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