Abivax Provides Update on Ulcerative Colitis (UC) Combination Therapy Program Strategy and Announces Early Preclinical Combination Data of Obefazimod and Etrasimod in Inflammatory Bowel Disease (IBD) Mouse Model

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- Abivax is actively conducting preclinical studies with multiple oral and injectable therapies and will report additional data in Q4 2024.
- Pre-clinical evaluation of obefazimod combined with etrasimod improved body weight protection and Disease Activity Index with a synergistic and statistically significant reduction of several cytokines (TNFa, IL-17, IL-6, IFNg) in the blood compared to each treatment alone.

PARIS, France, September 25, 2024, 10:00 p.m. CEST – Abivax SA (Euronext Paris & Nasdaq: ABVX) ("Abivax" or the "Company"), a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to stabilize the immune response in patients with chronic inflammatory diseases, announced today results of initial preclinical combination data of obefazimod combined with etrasimod in a mouse model of IBD.

"Despite progress and development of multiple new advanced targeted therapies in IBD, efficacy rates appear to have reached a ceiling. Fewer than half of patients achieve clinical remission, and many of those lose response over time. It is imperative for our field to explore rational and scientifically driven combination therapies to break through the efficacy ceiling, which in turn will lead to improved long-term outcomes for patients," **said David Rubin, MD Professor of Medicine and Chief, Gastroenterology, Hepatology and Nutrition at The University of Chicago**.

"Our goal for this program is to develop a fixed-dose combination therapy for UC patients that delivers best-in-disease state induction and maintenance efficacy, a safety profile on par with obefazimod, and an IP runway into the late 2040's", **said Marc de Garidel, CEO of Abivax**. He went on to say, "We believe that obefazimod's emerging safety and efficacy profile, with potentially best-in-disease maintenance efficacy, could provide a meaningful benefit to patients when taken as a monotherapy. Additionally, since obefazimod is an oral therapy that has thus far demonstrated a favorable safety profile, it is an attractive candidate to be combined with other mechanisms of action to attempt to break through the efficacy ceiling observed with advanced therapies."

Fabio Cataldi, MD Chief Medical Officer of Abivax provided key elements of the combination therapy program. "This program involves multiple stages. First, we will perform additional pre-clinical experiments evaluating the efficacy of obefazimod in combination with several other mechanisms of action. Based on our findings, we plan to select a candidate in 2025 and work towards developing a fixed dose combination to move into clinical development."

"We are setting a high bar for success and are excited about the promising data we are generating with this preclinical combination program," **Mr. de Garidel said**. "We are planning to present this data at an upcoming scientific conference and are actively conducting additional combination studies that address various disease pathways. We look forward to providing an update on our progress by year end."

Pre-Clinical Program and Initial Findings

Preclinical evaluation of obefazimod combined with etrasimod, was conducted in the T-cell adoptive transfer mouse model. In this study, CD4+CD45high or CD4+CD45low cells were intraperitoneally injected to 6-week-old male C57BL/6NRj-Rag2^{tm1Ciphe}/Rj mice (10 mice per group). The mice were then orally treated for 55 days with obefazimod or etrasimod alone or with the combination of both compounds. The results showed that treatment with the combination improved the response on body weight protection and Disease Activity Index with a synergistic and statistically significant reduction of several cytokines (TNFa, IL-17, IL-6, IFNg) in the blood compared to each drug alone.

About Obefazimod

Obefazimod, Abivax's lead investigational drug candidate, is an orally administered small molecule that was demonstrated to potentially enhance the expression of a single microRNA, miR-124. Phase 2 clinical trials in patients with UC have generated positive data, resulting in the initiation of a pivotal global Phase 3 clinical trial program (ABTECT Program), with first patients enrolled in the United States in October 2022. Initiation of a Phase 2b clinical trial in Crohn's disease is expected in Q3 2024, and exploration of potential combination therapy opportunities in UC is ongoing.

About Abivax

Abivax is a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory

mechanisms to stabilize the immune response in patients with chronic inflammatory diseases. Based in France and the United States, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of moderately to severely active ulcerative colitis. More information on the Company is available at www.abivax.com. Follow us on LinkedIn and on X, formerly Twitter, @Abivax.

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