
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES
EXCHANGE ACT OF 1934**

For the month of September 2024

Commission File Number: **001-41842**

Abivax SA

(Translation of registrant's name into English)

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75009 Paris, France

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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F []

On September 25, 2024, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit Index

Exhibit 99.1. [Press release dated September 25, 2024](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Abivax SA
(Registrant)

Date: September 25, 2024

/s/ Marc de Garidel
Marc de Garidel
Chief Executive Officer

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

- 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 (TNF-alpha, IL-17, IL-6, IFN-gamma) 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+CD45^{high} or CD4+CD45^{low} 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 (TNF-alpha, IL-17, IL-6, IFN-gamma) 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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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "expect," "plan," "potential," "will" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning or implying the therapeutic potential of Abivax's drug candidates, the availability and timing of preclinical data to support decision-making on therapy candidates for use in combination with obefazimod in UC, as well as the availability and timing of disclosure of preclinical data of any such combination therapy, the timing of initiation of clinical trials, obefazimod's potential, as monotherapy or in combination with other therapies, to provide meaningful benefit to patients suffering from UC, Crohn's disease, IBD or other indications, and other statements that are not historical fact. Although Abivax's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks, contingencies and uncertainties, many of which are difficult to predict and generally beyond the control of Abivax, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. A description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its universal registration document (Document d'Enregistrement Universel) and in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 5, 2024 under the caption "Risk Factors." These risks, contingencies and uncertainties include, among other things, the uncertainties inherent in research and development, future clinical data and analysis, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug candidate, as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates. Current results are not necessarily indicative of future results. Special consideration should be given to the potential hurdles of clinical and pharmaceutical development including further assessment by the company and regulatory agencies and IRBs/ethics committees following the assessment of preclinical, pharmacokinetic, carcinogenicity, toxicity, CMC and clinical data. Furthermore, these forward looking statements, forecasts and estimates are only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Abivax disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law. Information about pharmaceutical products (including products currently in development) that is included in this press release is not intended to constitute an advertisement. This press release is for information purposes only, and the information contained herein does not constitute either an offer to sell, or the solicitation of an offer to purchase or subscribe securities of the Company in any jurisdiction. Similarly, it does not give and should not be treated as giving investment advice. It has no connection with the investment objectives, financial situation or specific needs of any recipient. It should not be regarded by recipients as a substitute for exercise of their own judgment. All opinions expressed herein are subject to change without notice. The distribution of this document may be restricted by law in certain jurisdictions. Persons into whose possession this document comes are required to inform themselves about and to observe any such restrictions.