Abivax Announces Patient-Reported Outcomes Data from the Phase 3 ABTECT Induction Trials of Obefazimod, Demonstrating Significant Improvements in Quality of Life for Patients with Moderate-to-Severely Active Ulcerative Colitis

November 3, 2025

Abivax Announces Patient-Reported Outcomes Data from the Phase 3 ABTECT Induction Trials of Obefazimod, Demonstrating Significant Improvements in Quality of Life for Patients with Moderate-to-Severely Active Ulcerative Colitis

- *Improvements across all patient reported outcomes (PROs) were observed from baseline to Week 8 in all PRO instruments utilized in the ABTECT induction trials evaluating bowel urgency, sleep interruption, fatigue, quality of life, and work productivity for both 50mg and 25mg once-daily obefazimod.*

- *At week 8 in the ABTECT 1 & 2 trials, 37% of patients taking once daily 50mg obefazimod reported no bowel urgency (BU) compared to 18.1% of patients in the placebo group (18.9, p<0.0001[1]), with improvements in BU observed as early as week two*

- *47.6% of patients on 50mg obefazimod reported no nocturnal bowel movements (NBM) at week 8 compared to 24.7% in the placebo group (23.1, p<0.0001[1])*

- *In the 50 mg group 17.1% of patients reported fatigue remission as measured with the Fatigue Numerical Rating Scale (NRS) at week 8, compared to 7.7% in the placebo group (9.5, p=0.0001[1])*

- *Detailed data across PROs, including data for both 25mg and 50mg groups, to be submitted for presentation at upcoming medical meetings*

PARIS, France – November 3, 2025 – 10:05 PM CET – Abivax SA (Euronext Paris: FR0012333284 – ABVX / 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, today announced patient-reported outcomes (PRO) from its Phase 3 ABTECT 8-week induction trials evaluating obefazimod in adult patients with moderate-to-severely active ulcerative colitis (UC). In addition to the trials' clinical efficacy endpoints, PRO instruments are important in determining how patients perceived changes in their symptoms, quality of life, and activities of daily living.

"Ulcerative colitis can be a devastating condition that affects every aspect of a person's daily life, including their ability to work, socialize, and maintain their emotional well-being," **said Marla Dubinsky, MD[2], Professor of Pediatrics and Medicine, Chief, Division of Pediatric Gastroenterology and Nutrition, Co-Director, Susan and Leonard Feinstein IBD Clinical Center, Mount Sinai Kravis Children's Hospital, Icahn School of Medicine Mount Sinai New York.** *"For these patients, improvement isn't just about controlling inflammation, it's about regaining a sense of normalcy. That's why measures of quality of life are so important when evaluating potential new therapies so that we also capture the outcomes that truly matter to patients, and bowel urgency is one of these key factors. The consistency of improvements across all PRO instruments utilized in this program underscores the meaningful benefit obefazimod provided to patients' daily experience and supports the positive Phase 3 efficacy results observed at week 8. Together, these results highlight obefazimod's potential to meaningfully advance care for patients with UC."*

PRO instruments evaluated in the ABTECT trials include:

- Bowel urgency
- Nocturnal bowel movement
- Fatigue numerical rating scale (NRS)
- Fatigue and ability to function (FACIT-F)
- Inflammatory bowel disease questionnaire (IBDQ)
- Overall quality of life (EQ-5D-5L)
- Workplace productivity (WPAI Domains)

Detailed analysis of these PROs will be submitted for presentation at an upcoming medical conference.

Marc de Garidel, MBA, Chief Executive Officer of Abivax, commented, *"The data shared today further support obefazimod's*

potential as a meaningful treatment option for patients with ulcerative colitis (UC). Our development efforts, guided by the recognized need for more effective and tolerable long-term therapies, are focused on advancing treatments that can significantly improve patients' quality of life. Taken together with the previously reported positive ABTECT 8-week induction trial results, we are one step closer to realizing this goal. We will be submitting more detailed aspects of this dataset for presentation at an upcoming medical meeting and look forward to sharing results from our 44-week maintenance trial in the second quarter of 2026."

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.

Contact:
Patrick Malloy
SVP, Investor Relations
Abivax SA
patrick.malloy@abivax.com
+1 847 987 4878

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business. Words such as "anticipate," "expect," "potential" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the Company's anticipated timing for data readouts of its ABTECT induction and maintenance clinical trials and the potential therapeutic benefit of obefazimod. 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 its Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 24, 2025 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, and the availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements. 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 made 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 for 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.

1 ABTECT-1&2 pooled analysis; all p-values are nominal. Endpoints are secondary and not alpha controlled.
2 Marla Dubinsky, MD is a paid consultant for Abivax.

ABIVAX

Source: Abivax