Abivax Announces Positive Pre-NDA Interaction with the FDA for Obefazimod

Company remains on track to submit its first New Drug Application for obefazimod for the treatment of moderately to severely active ulcerative colitis by the end of 2026

PARIS, France – July 30, 2026 – 10:05 p.m. CEST – 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 the successful completion of its positive pre-New Drug Application (NDA) interaction with the U.S. Food and Drug Administration (FDA) for obefazimod for the treatment of adults with moderately to severely active ulcerative colitis (UC). Constructive FDA feedback resulted in alignment on the Company's planned NDA submission strategy and supported the planned content and format of the NDA submission. Abivax remains on track to submit its first NDA for obefazimod by the end of 2026.

Marc de Garidel, MBA, Chief Executive Officer of Abivax said: *"Achieving alignment with the FDA on our NDA submission strategy marks an important milestone as we prepare to submit Abivax's first New Drug Application for obefazimod. We appreciate the Agency's constructive feedback, which reinforces our confidence in the path toward filing. This progress builds on the positive Phase 3 ABTECT program results announced earlier this year, which continue to support obefazimod's potential in ulcerative colitis as we work toward completing our NDA submission by the end 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.

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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. Words such as "anticipate," "expect," "on track," "potential," "will" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the potential therapeutic benefit of obefazimod and obefazimod's potential to be a first-in-class therapy for ulcerative colitis, the timing of regulatory filings including an NDA submission for obefazimod in ulcerative colitis, the potential U.S. commercialization of obefazimod, 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 its Annual Report on Form 20-F for the fiscal year ended December 31, 2025 filed with the U.S. Securities and Exchange Commission on March 23, 2026, 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 labeling 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.