Abivax Announces Late-Breaking Presentation of 8-Week ABTECT Trial Results with Updated Safety Data

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- *50 mg once-daily dose of obefazimod led to a pooled 16.4% (p<0.0001) placebo-adjusted clinical remission rate at Week 8; met primary and all key secondary endpoints in both ABTECT 1 and ABTECT 2*
- *ABTECT trials enrolled refractory patient population with 47% of participants having prior inadequate response to advanced therapy, among whom 21% had prior inadequate response to JAK inhibitor therapy*
- *Obefazimod treatment was well tolerated with no new safety signals identified for both the 25mg and 50mg doses*
- *Abivax to present a second late-breaking abstract on October 6. Management to host a conference call to discuss results of both late-breaking abstracts at 9am ET / 3pm CET on October 6.*

PARIS, France – October 05, 2025 – 5:00 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 results from the first of two late-breaking presentations at the United European Gastroenterology (UEG) Meeting in Berlin, Germany. The presentation includes results from Abivax's Phase 3 ABTECT 8-Week Induction Trials investigating obefazimod for the treatment of moderate-to-severely active ulcerative colitis, including previously reported findings and additional safety data at week 8.

"*There is an urgent need for new therapies to treat ulcerative colitis that deliver durable efficacy, safety, and the simplicity of oral, once-daily dosing*," **said Bruce Sands, MD*, Professor of Medicine, Icahn School of Medicine at Mount Sinai.** *"The ABTECT Trials enrolled individuals with advanced disease, including many who had failed multiple lines of advanced therapy and a significant percentage of patients with prior JAK inhibitor failure. The refractory nature of this population underscores the significance of the results presented today*."

A total of 1272 patients were enrolled across the ABTECT 1 & 2 trials. In the pooled full data set across ABTECT 1 & 2, no signal for serious, severe, or opportunistic infections or malignancies was observed. The most commonly reported TEAEs were headache (6%-placebo, 16%-25mg, 24.1%-50mg) with <1% of headaches leading to study discontinuation (0.3% at 25mg; 1.1% at 50mg), and nausea (1.3% in placebo, 5.0% at 25mg, 7.2% at 50mg).

Results from the ABTECT-1 and ABTECT-2 trials demonstrated that obefazimod met its FDA primary endpoint of clinical remission at Week 8 in the 50 mg once-daily dose regimen for both trials. Individually, ABTECT-1 showed a placebo-adjusted clinical remission rate of 19.3% (p<0.0001) and ABTECT-2 demonstrated 13.4% (p=0.0001), each at the 50 mg once-daily dose, with all key secondary efficacy endpoints being met.

*Bruce Sands, MD is a paid consultant for Abivax

Investor Conference Call and Webcast

Abivax management will host an investor and analyst conference call tomorrow on October 6, 2025, at **9:00 a.m. ET / 3:00 p.m. CET** to discuss the topline results. To participate, please use the following dial-in or webcast link:

https://edge.media-server.com/mmc/p/tjj8438w

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 and financial objectives. 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 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.