Abivax Announces First Patient Enrolled in ENHANCE-CD, the Phase 2b Trial of Obefazimod in Crohn's Disease

October 3, 2024

PARIS, France, October 3, 2024 – 10:00 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 first patient was enrolled in its Phase 2b ENHANCE-CD (NCT06456593) trial evaluating obefazimod in patients with Crohn's disease (CD).

The multicenter, double-blind, randomized, placebo-controlled trial will evaluate the efficacy and safety of obefazimod, administered once daily, in adults with moderately to severely active Crohn's disease.

Fabio Cataldi, MD, Abivax Chief Medical Officer, said, *"The enrollment of the first patient in our Phase 2b trial marks a significant step forward in meeting the need for a convenient, oral, once-daily treatment option for people with moderately to severely active Crohn's disease. This milestone brings us closer to addressing the unmet needs of patients seeking effective therapies with fewer burdens on their daily lives."*

Trial Design

This trial has 3 treatment phases: a 12-Week Induction Phase, a 40-Week Maintenance Phase, and a 48-Week Extension Phase. The objective is to evaluate the efficacy and safety of obefazimod compared to placebo as induction and maintenance therapy in subjects with moderately to severely active CD after inadequate response (no response, loss of response, or intolerance) to conventional therapies and/or advanced therapies. The primary objective for the 48-Week Extension Phase is to evaluate the safety and tolerability of obefazimod compared to placebo in subjects who are enrolled in the Extension Phase.

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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. A Phase 2b clinical trial in Crohn's disease is ongoing, with the first patient enrolled in October 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 "continue," "could," "expect," "goal," "intend," "objective," "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, including obefazimod's potential to provide meaningful benefit to patients suffering from CD, 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. 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.