Abivax Reports Positive Interim Efficacy and Safety Analysis of Once-Daily 25mg Obefazimod in Moderate to Severe Ulcerative Colitis Patients After 2-Years of Open-Label Maintenance

October 3, 2024

- Patients treated with a de-escalated dose of 25 mg of obefazimod once daily demonstrated maintenance of clinical remission at weeks 48 and 96
- Efficacy and safety demonstrated out to six years of treatment
- The treatment was well-tolerated, with a safety profile consistent with previous studies and no new safety signals detected

PARIS, France, October 3, 2024, 8:30 a.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 the results of an interim efficacy and safety analysis of an open-label maintenance (OLM) study that enrolled patients with UC at the conclusion of the Phase 2a and Phase 2b OLM studies, where they had received obefazimod 50mg once daily. The data demonstrated maintenance of clinical remission and a safety profile consistent with prior studies of oral, once-daily obefazimod when administered at a reduced dose of 25mg for up to an additional two years.

"These important data further support the potential of obefazimod as a promising therapeutic option for patients with UC," said **Marla Dubinsky, MD, Co-Director, Susan and Leonard Feinstein IBD Clinical Center at Icahn School of Medicine at Mount Sinai New York**. *"The results observed at a lower dose are particularly encouraging, as clinicians often like to have the option to de-escalate dosing once patients achieve remission".*

In this open-label maintenance study, patients who had completed the 4-year Phase 2a or 2-year Phase 2b OLM studies, where they had received 50 mg of once-daily obefazimod, were given the opportunity to continue receiving obefazimod at a reduced dose of 25mg daily for up to five additional years (provided they met the eligibility criteria of Mayo Endoscopic Subscore = 0 or 1). A total of 130 patients entered the study, as of Sep 11, 2024, the data cut-off date, 113 have been evaluated out to 48 weeks and 74 have undergone the full 96-week evaluation.

At study baseline, 89% (116/130) of patients were in clinical remission. At weeks 48 and 96 of treatment, 84% (95/113) and 87% (64/74) of patients evaluated were in clinical remission, respectively. Similarly, 92% (119/130) of patients were in symptomatic remission at study baseline. At weeks 48 and 96, 91% (103/113) and 92% (68/74) of patients evaluated were in symptomatic remission, respectively. Similar trends were observed with other efficacy analyses.

Silvio Danese, MD, Professor of Gastroenterology at the San Raffaele University, Milan, Italy, stated *"For patients with UC, a significant need exists for an oral treatment option that is not only well-tolerated and convenient, but that provides maintenance of remission over a long period of time. The obefazimod data released today, with patients maintained for up to 6 years of treatment, provides me with great hope that we are getting closer to meeting that significant need."*

The safety results were consistent with previous studies, with no new safety signals detected. Patient retention rates were high, with only 12% (16/130) of patients discontinuing in the first year and 5% (6/114) discontinuing during the second year of treatment (33 patients have not reached week 96 as of Sept 11, 2024, the data cutoff date.

"The maintenance of clinical remission and the promising tolerability data observed to date, underscores the potential of obefazimod as a treatment for ulcerative colitis. We look forward to presenting this data at an upcoming medical meeting," said **Fabio Cataldi, MD, Chief Medical Officer, Abivax**.

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 Q4 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 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.