Abivax announces update to obefazimod Phase 2b clinical development program in moderately to severely active Crohn's disease

February 2, 2024

- *Obefazimod Crohn's Disease (CD) IND filed with the FDA in December 2023 and cleared to proceed*
- *In alignment with FDA feedback, Abivax to modify CD trial design and conduct dose ranging Phase 2b clinical trial*
- *Start of patient enrollment planned for Q3 2024*
- *12-week induction data read-out expected in 2H 2026*

PARIS, France, February 2, 2024, 8:30 a.m. CET – 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, today announced modifications to its Phase 2 development program of obefazimod in CD, to align with recent FDA feedback. The start of patient enrollment is expected in Q3 2024.

Sheldon Sloan, MD, M Bioethics, CMO of Abivax, says: *"The IND clearance by the FDA allows Abivax to move forward with the development of obefazimod for the treatment of Crohn's disease. The revised trial design incorporates FDA feedback, which we believe provides a more efficient pathway to a future NDA submission. We are excited to begin the obefazimod CD program, which has the potential to provide a meaningful benefit to patients in a therapeutic area with a high unmet medical need."*

The obefazimod Phase 2b clinical trial in moderately to severely active CD is a double-blind placebo-controlled trial, evaluating three obefazimod doses. The trial design consists of a 12-week induction period and a subsequent 40-week maintenance period.

The revised trial design takes into account FDA recommendations provided in the frame of an initial Phase 2a IND submission. These adjustments to the obefazimod CD clinical program are not expected to have an impact on the overall program budget and projected supplemental New Drug Application (sNDA) submission timeline.

The corporate presentation on www.abivax.com has been updated to reflect these changes.

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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 US, 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.

Contacts:

Abivax Communications	Abivax Investor Relations
Regina Jehle	Patrick Malloy
regina.jehle@abivax.com	patrick.malloy@abivax.com
+33 6 24 60 69 63	+1 847 987 4878

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This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "design," "expect," "forward," "future," "potential," "plan," "project" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the planned enrollment date for the Company's Phase 2b clinical trial in moderately to severely active CD, the Company's expectations regarding the availability of data and timing of reporting results from such trial, the impact of the adjustments to the obefazimod CD clinical program on the overall program budget and projected supplemental New Drug Application (sNDA) submission timeline, 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). 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

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