Abivax Announces Completion of Enrollment for the Phase 3 ABTECT Trials in Patients with Moderately to Severely Active Ulcerative Colitis

April 29, 2025

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- *The Phase 3 ABTECT trials (Studies 105 and 106) evaluating obefazimod in patients with moderately to severely active ulcerative colitis successfully enrolled 1,275 participants, exceeding the target enrollment of 1,224 by 4%.*
- *Top-line results from the 8-week induction trials anticipated in Q3 2025, with 44-week maintenance data on track for Q2 2026 and, if successful, NDA submission planned for H2 2026.*
- *Blinded baseline characteristics align with pre-specified target population and are consistent with Phase 2b UC trial participant characteristics*
- *Cash runway through ABTECT induction trials readout and into Q4 2025*

PARIS, France – April 29, 2025 – 10:05 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 the completion of enrollment for the Phase 3 ABTECT trials in patients with moderately to severely active ulcerative colitis.

Marc de Garidel, Chief Executive Officer of Abivax, commented:
"Completing enrollment for our Phase 3 ABTECT trials—one of the largest and fastest enrolling ulcerative colitis programs of its kind ever conducted—is a landmark achievement for bothAbivax and the UC patient community. Obefazimod has already shown compelling potential to address the significant unmet needs of patients with moderately to severely active disease. We remain fully committed to advancing this pivotal program: we expect to report top-line induction results in Q3 2025, followed by comprehensive long-term maintenance data in Q2 2026. Should these data confirm obefazimod's safety and efficacy, we plan to submit a New Drug Application to the FDA in the second half of 2026, bringing us ever closer to delivering a desperately needed new therapeutic option."

Fabio Cataldi, MD, Chief Medical Officer of Abivax added: *"Importantly, the blinded baseline characteristics of participants in the Phase 3 ABTECT trials closely align with those observed in our Phase 2b trial. This consistency reinforces our confidence in obefazimod's potential efficacy and safety profile as we advance through the pivotal stage of its clinical development."*

Trial Participant Baseline Characteristics: ABTECT Phase 3 vs. Obefazimod Phase 2b

	ABTECT Phase 3	Phase 2b
Study Participants	1,275	252
Baseline MMS (7-9)	65%	71%
Prior Advanced Therapy Failure	48%	48%
Corticosteroids	42%	52%
Geographic Distribution	North America : 10% Western / Central Europe: 22% Eastern Europe:38% Asia:24% ROW: 6%	North America : 1% Western/Central Europe: 33% Eastern Europe: 66%

ABTECT Phase 3 Trials Update:

- **Enrollment Completion:** 1,275 participants successfully enrolled into two Phase 3 pivotal studies across multiple clinical sites.
- **Maintenance Study:** To date, 597 of the 1,111 participants—comprising both completers of the induction study and those

who were randomized but discontinued during the induction phase—have been enrolled in Part 1 (the 'responder arm') of the 44-week maintenance trial. This exceeds the minimum enrollment required to meet the statistical power assumptions. The Maintenance Study will continue to enroll participants through completion of induction study (end of June 2025).

- **Top-Line Results:** Induction trials topline data expected in Q3 2025, with 44-week maintenance topline data expected in Q2 2026.
- **Participant Characteristics:** Blinded baseline data aligns with the target population identified in the Phase 2b UC study.
- **Safety Monitoring:** No new safety signals observed in the latest Data Safety Monitoring Board (DSMB) review conducted on April 25, 2025.
- **Regulatory Strategy:** Pending positive results, a New Drug Application (NDA) submission in the US is targeted for H2 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 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 Company's anticipated timing for top-line data readout of its ABTECT clinical trials and NDA submission, the potential therapeutic benefit of obefazimod, and the Company's expected cash runway. 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.

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