



Abivax Provides 2026 Corporate Outlook

January 7, 2026

Abivax Provides 2026 Corporate Outlook

- *New market insights indicate significant future expansion of the ulcerative colitis (UC) market, with obefazimod well positioned to become a future market leader in the IBD space*
- *ABTECT Phase 3 Data Safety Monitoring Board (DSMB) meeting on December 18, 2025, found no new safety signals with over 80% of participants having completed the 44-week double blind maintenance trial*
- *ABTECT-UC Phase 3 maintenance topline results expected late Q2 2026, with a subsequent US regulatory filing planned for late 2026*
- *ENHANCE-CD Phase 2b induction trial of obefazimod in moderate-to-severely active Crohn's disease (CD) ongoing; induction results expected late 2026*
- *22 abstracts accepted for upcoming February 2026 European Crohn's and Colitis Organization (ECCO) conference including oral presentation of obefazimod impact on fibrosis in in-vitro and preclinical models*
- *Cash runway expected into Q4 2027, after full debt reimbursement in Q4 2025*

PARIS, France – January 7, 2026 – 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 its 2026 corporate outlook, highlighting new market insights, progress in the ABTECT-UC and ENHANCE-CD trials, and advances in its therapeutic pipeline. Updates from the ABTECT Phase 3 maintenance trial evaluating obefazimod for the treatment of moderate-to-severely active UC reinforce the therapy’s safety profile and inform potential future combination strategies.

Marc de Garidel, MBA, Chief Executive Officer of Abivax, commented: *“As I reflect on our advances in 2025, I am beyond thankful for the patients and physicians who have helped advance our trials and for the Abivax employees and investors who supported this progress. This past year was a monumental one for Abivax as we announced positive data from our ABTECT Phase 3 8-week induction trial demonstrating obefazimod’s safety and potential as a first-in-class oral therapy for UC, we shared updates at major international meetings, and we closed a successful significant fundraising round. In 2026, I look forward to continuing this momentum as we evaluate the ABTECT-UC Phase 3 maintenance and ENHANCE-CD Phase 2 induction data and identify new opportunities for advancement of our pipeline. The findings shared today from the updated market research and DSMB safety analyses demonstrate the significant opportunity we have for making a real impact for the millions of patients inadequately addressed by current treatment options.”*

LOOKING AHEAD TO 2026:

Ulcerative Colitis Market Opportunity

Multiple third-party industry analyses forecast significant growth in the ulcerative colitis (UC) market over the coming years, driven by increased use of advanced therapies and the launch of innovative mechanisms of action (MOAs). In one recently published report, worldwide UC sales are expected to more than double, increasing from \$9.2 billion in 2025 to \$21.2 billion by 2032.

In this context, market research following the announcement of the ABTECT Phase 3 induction results in July 2025 indicates that obefazimod may emerge as the future market leader in UC, potentially outperforming both currently approved therapies and anticipated future entrants, including TL1A inhibitors and oral IL-23 agents.

The research estimated that roughly 500K patients within the United States are currently on conventional therapies (5ASAs/corticosteroids), with approximately 60% of these patients being moderate/severe (~300K patients). Physicians indicated they would likely initiate treatment with obefazimod for this population where reluctance to advanced therapies hinder their use.

ABTECT Phase 3 DSMB Update, Maintenance Topline Results, and Expected US Filing Timing

The ABTECT Phase 3 DSMB meeting occurred on December 18, 2025, and reported no new safety signals with over 80% of participants having completed the 44-week double blind maintenance phase of the trial.

Topline results from the ongoing ABTECT Phase 3 maintenance trial are expected in late Q2 2026 which has the potential to further demonstrate the durability of obefazimod treatment in UC and extended duration of therapy versus the currently available

treatment options.

Ongoing New Drug Application (NDA) preparation includes planned engagement with the FDA in anticipation of planned filing in late 2026.

Pipeline Advancement

Obefazimod has a first-in-class mechanism of action that targets the site of inflammation and, together with preclinical evidence of a clear anti-fibrotic effect in Crohn's disease, underscores its potential as a differentiated treatment option for patients with the condition. Detailed results, including 22 abstracts, will be shared at the 2026 European Crohn's and Colitis Organization (ECCO) Annual Meeting taking place in Stockholm, Sweden on February 18-21, 2026.

The ENHANCE-CD Phase 2b, designed to evaluate the safety and efficacy of obefazimod in patients with moderate-to-severely active Crohn's disease (CD), is actively progressing. The 12-week induction trial results are anticipated in late 2026 and will help inform the design of subsequent registrational studies.

Throughout 2026, initial preclinical results from ongoing studies evaluating obefazimod in combination with other agents (currently targeted combination MOAs include IL-23, a4b7, PDE-4 and AhR) will be shared, with a lead combination candidate selected to advance into development by year-end.

The company is also continuing to evaluate follow-on miR-124 enhancers in various chronic inflammatory models to further extend the mechanistic framework established with obefazimod. In parallel, the team is evaluating potential in-licensing opportunities for innovative, mechanistically complementary assets in inflammatory bowel disease to strengthen its portfolio.

Marc de Garidel continued: *"This past year we have worked diligently to advance obefazimod in both ulcerative colitis and Crohn's disease, showcasing the immense opportunity we have in expanding the current market and the potential for movement into first- and second-line therapy options. With our recently secured funding poised to support us into Q4 2027, we are now focused on completing our ABTECT Phase 3 maintenance trial to support potential NDA filing by the end of the year, completing our Phase 2b Crohn's disease trial, and evaluating additional opportunities for advancement across our pipeline. We look forward to sharing additional updates throughout the year as we aim to offer a safer, more effective and durable treatment option for those impacted by chronic inflammatory diseases like UC and Crohn's."*

Abivax 2026 Financial Reporting Calendar

March 23, 2026:	Fiscal Year 2025 Financial Results
June 1, 2026:	Q1 2026 Financial Results
June 5, 2026:	Annual General Meeting / Extraordinary General Meeting
September 14, 2026:	H1 2026 Financial Results
December 14, 2026:	Q3 2026 Financial Results

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.

Contact:

Patrick Malloy
SVP, Investor Relations
Abivax SA
patrick.malloy@abivax.com
+1 847 987 4878

Media Contacts:

LifeSci Communications
Karissa Cross, Ph.D.
Associate Director
kcross@lifescicomms.com

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business. 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 expectations for 2026, including the Company's anticipated timing for topline results of its ABTECT Phase 3 maintenance and timing of the Company's planned NDA filing, results of its ENHANCE-CD Phase 2 induction clinical trials, the potential therapeutic benefit and market opportunity of obefazimod, planned announcement of combination therapy, progress of the Company's follow-on compound and 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.