



## Abivax Presents First Evidence of Anti-Fibrotic Activity for Obefazimod Alongside New Clinical Efficacy and Safety Analyses in Inflammatory Bowel Disease at ECCO 2026

- *22 abstracts presented at European Crohn's and Colitis Organization's (ECCO) 21<sup>st</sup> Annual Congress illustrate the depth and breadth of data supporting obefazimod's potential in inflammatory bowel disease*
- *Anti-fibrotic effects of obefazimod were observed in both a preclinical human fibroblast model and in an in vivo animal model, suggesting potential to address a major unmet need in Crohn's disease*
- *A pooled analysis of safety data from ABTECT-1 and ABTECT-2 induction trials demonstrates a favorable safety profile with rates of serious treatment emergent adverse events and study discontinuation similar to placebo*
- *Symptomatic response of obefazimod was observed as early as week 1 (first time point evaluated) with symptomatic remission observed at week 2 (nominally significant p-value <0.05) in a pooled analysis of ABTECT-1 and ABTECT-2*
- *Biomarker data from ABTECT-1 and ABTECT-2 induction trials indicate upregulation of miR-124 and reduction of key inflammatory cytokines (IL-17A and IL-6) toward homeostatic levels*

**PARIS, France – February 21, 2026 – 12:00 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 novel preclinical and clinical data for obefazimod as part of the presentations at The European Crohn's and Colitis Organization's (ECCO) 21st Annual Congress. These data further expand the evidence base supporting development of obefazimod for inflammatory bowel disease, highlighting its anti-fibrotic potential in Crohn's disease (CD), a favorable safety and tolerability profile, rapid onset of symptomatic relief, and additional evidence supporting its mechanism of action in restoring immune balance through upregulation of miR-124.

**Marc de Garidel, MBA, Chief Executive Officer of Abivax, commented:** *"The robust data presented at ECCO this week reinforce obefazimod's unique and differentiated profile. The anti-fibrotic findings, taken together with the additional clinical efficacy, safety, and biomarker data presented, strengthen our confidence in obefazimod's potential across UC and CD. As we look toward the upcoming Phase 3 maintenance trial readout in Q2 2026 and the Phase 2b ENHANCE-CD trial readout in Q4 2026, we remain focused on translating this data into real-world benefits for patients with IBD."*

**Fabio Cataldi, MD, Chief Medical Officer of Abivax, added:** *"The emerging preclinical evidence of anti-fibrotic activity is particularly compelling, as fibrosis remains an area of profound unmet need. Combined with the favorable safety and tolerability profile of obefazimod, we believe this*



*growing evidence base positions obefazimod as a compelling oral therapy with the potential to address multiple dimensions of disease not yet fully managed by current therapies.”*

## **HIGHLIGHTED PRESENTATIONS:**

The 22 abstracts presented at ECCO 2026, including subgroup analyses from the Phase 3 ABTECT induction trials illustrating obefazimod’s clinical activity across a wide range of patient subpopulations, can be accessed at: <https://www.abivax.com/publications/congress-publications>

- **Obefazimod shows first evidence of anti-fibrotic activity in preclinical models of inflammatory bowel disease** (Danese S et al. OP30, ECCO 2026)
  - In an *in vitro* human fibroblast model, obefazimod led to a ~50% reduction in a biomarker of active fibrosis (Pro-C3) ( $p < 0.0001$ ) and a ~30% reduction in a fibroblast activation marker ( $\alpha$ SMA) ( $p < 0.0001$ )
  - In an *in vivo* animal model, obefazimod exhibited dual anti-inflammatory and anti-fibrotic effects leading to rapid improvement in markers of disease activity
  - Obefazimod demonstrated anti-inflammatory effects when initiated as a fibrosis preventative (day 5) or fibrosis treatment (day 20):
    - ~25% ( $p < 0.0001$ ) and ~50% ( $p < 0.0001$ ) reduction in Disease Activity Index, with late (day 20) and early (day 5) treatment, respectively
    - ~35% ( $p < 0.0001$ ) and ~65% ( $p < 0.0001$ ) reduction in histologic ulceration and inflammation scores, with late and early treatment, respectively
  - Obefazimod demonstrated anti-fibrotic effects when initiated as a fibrosis preventative (day 5) or fibrosis treatment (day 20):
    - ~45% ( $p < 0.0001$ ) and ~55% ( $p < 0.0001$ ) reduction in Collagen Deposition (fibrosis marker), with late and early treatment, respectively
    - ~40% ( $p < 0.0001$ ) and ~50% ( $p < 0.0001$ ) reduction in  $\alpha$ SMA (fibroblast activation marker), with late and early treatment, respectively
    - ~60% ( $p < 0.0001$ ) and ~90% ( $p < 0.0001$ ) reduction in histologic Fibrosis Score, with late and early treatment, respectively
- **Integrated summary of safety of obefazimod in Phase 3 ABTECT induction trials** (Seidler U et al. P0712, ECCO 2026)
  - Of the 1,272 patients randomized and treated with Obe-50mg, Obe-25mg, or placebo (PBO), the overall rates of serious treatment emergent adverse events (TEAEs) was comparable across all groups (Obe-50mg: 3.1%; Obe-25mg: 2.2%; PBO: 3.2%)
  - TEAEs leading to study discontinuation occurred at similar rates across all groups (Obe-50mg, 4.7%; Obe-25mg, 1.9%; PBO, 4.1%)
  - Headaches were one of the most frequent TEAEs and were reported to be mild, transient, and short in duration (median: 2-3 days) and rarely leading to discontinuation (0-1.1%)



- **Early symptomatic improvements with obefazimod in patients with moderately to severely active ulcerative colitis** (Armuzzi A et al. P0923, ECCO 2026)
  - A greater proportion of patients receiving obefazimod (50mg or 25mg) versus PBO achieved symptomatic response from week 1 and symptomatic remission from week 2 increasing through week 8
  - In a pooled analysis of the Phase 3 ABTECT-1 and ABTECT-2 induction trials, both Obe-50mg and Obe-25mg produced reductions in rectal bleeding subscores and stool frequency subscores versus PBO starting from week 1 and reaching a nominally significant difference by week 2 (*p-value* <0.05)
  - Improvement in symptoms consistently increased through week 8
- **Obefazimod enhances miR-124 expression in blood and colon tissue and reduces the key inflammatory cytokines IL-17A and IL-6 in serum of patients with moderately to severely active ulcerative colitis** (Siegmond B et al. P0868, ECCO 2026)
  - In both Phase 3 ABTECT induction trials, Obe-25mg and Obe-50mg significantly enhanced expression of miR-124 in blood (unadjusted  $p < 0.0001$  vs. PBO) and in rectal and sigmoidal tissue (unadjusted  $p < 0.0001$  vs. PBO) at week 8
  - At week 8, Obe-25mg and Obe-50mg significantly reduced IL-17A levels in serum (unadjusted  $p < 0.0001$  vs. PBO); Obe-25mg ( $p=0.0150$  vs. PBO) and Obe-50mg ( $p=0.0039$  vs. PBO) decreased IL-6 levels in serum
  - miR-124 mechanism of action allows for partial reduction of inflammatory cytokines IL-17 and IL-6 toward homeostatic levels without completely blocking these pathways

**Professor Silvio Danese, Director of the Gastroenterology and Digestive Endoscopy Unit of the IRCCS San Raffaele Hospital, added:** *"For patients living with inflammatory bowel disease, long-term disease control and preservation of bowel function are critical. Seeing data that address not only clinical response and safety, but also biological activity and fibrosis, is encouraging. If these findings continue to translate clinically, they may represent a meaningful advancement for patients who currently have limited options."*

## **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](mailto:patrick.malloy@abivax.com)  
+1 847 987 4878



## **Media Contacts:**

LifeSci Communications

Jon Pappas

SVP, Head of Media Relations

[LSC\\_ABIVAX@lifescicomms.com](mailto:LSC_ABIVAX@lifescicomms.com)

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*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 potential therapeutic benefit of obefazimod and the expected availability and timing of results from the Phase 3 maintenance trial and Phase 2b ENHANCE-CD trial of obefazimod. 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.*