
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of June 2026

Commission File Number: 001-41842

Abivax SA

(Translation of registrant's name into English)

7-11 boulevard Haussmann
75009 Paris, France
+33 (0) 1 53 83 08 41

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Positive Topline Results from Part 2 of Phase 3 ABTECT 44-Week Maintenance Trial

On June 29, 2026, Abivax SA (the “Registrant” or the “Company”) announced positive topline results from Part 2 of its Phase 3 ABTECT 44-week maintenance trial evaluating obefazimod, the Company’s potential first-in-class oral miR-124 enhancer, in moderate to severely active ulcerative colitis (“UC”). Part 2 of the Phase 3 maintenance trial enrolled patients who either did not achieve clinical response following induction treatment or who experienced disease relapse during the re-randomized maintenance trial (Part 1), expanding both the efficacy and safety results in a more refractory patient population than the registrational maintenance cohort. The additional safety results generated through Part 2 expand the Phase 3 maintenance database and provide important context for interpreting the safety findings reported following the Maintenance Part 1 readout.

Among patients who failed to achieve clinical response after 8 weeks of induction, continued treatment with obefazimod resulted in clinically meaningful rates of clinical, endoscopic, and combined histologic-endoscopic endpoints at Week 44. Patients treated continuously with 50 mg obefazimod demonstrated the strongest outcomes across all endpoints, including clinical remission (37.2%), clinical response (61.5%), endoscopic improvement (48.0%), Histologic-Endoscopic Mucosal Improvement (“HEMI”) (44.6%), and endoscopic remission (34.5%). These findings suggest that a clinically meaningful proportion of patients who do not initially respond may still derive substantial benefit from longer treatment exposure.

Part 2 Induction Non-Responders – Exploratory Endpoints

	25 mg (N=81)	50 mg (N=148)
Clinical Remission	23.5%	37.2%
Clinical Response	50.6%	61.5%
Endoscopic Improvement	28.4%	48.0%
HEMI	23.5%	44.6%
Endoscopic Remission	22.2%	34.5%

Among patients who relapsed during Part 1 of the maintenance trial, re-treatment with 50 mg obefazimod resulted in meaningful rates of clinical remission, clinical response, endoscopic improvement, HEMI and endoscopic remission by Week 44. Patients who achieved clinical response with obefazimod during induction and relapsed after being re-randomized to placebo in Part 1 of the maintenance trial were treated with open-label 50 mg obefazimod and achieved clinical response and remission rates of 69.7% and 45.0%, respectively, while patients who relapsed on 25 mg and escalated to 50 mg achieved clinical response and clinical remission rates of 66.7% and 45.5%, respectively. These findings demonstrate the potential for obefazimod to re-establish disease control following relapse and support a flexible maintenance treatment strategy.

Part 1 Relapsers – Exploratory Endpoints

	Placebo (N=109)	25 mg (N=33)
	50 mg	50 mg
Clinical Remission	45.0%	45.5%
Clinical Response	69.7%	66.7%
Endoscopic Improvement	54.1%	45.5%
HEMI	47.7%	39.4%
Endoscopic Remission	32.1%	24.2%

In Part 2, four total non-melanoma skin cancers (“NMSC”) events were reported, two in the 25 mg arm and two in the 50 mg arm which all occurred in patients with established NMSC risk factors including advanced age, thiopurine use, prior skin cancer history and failure of multiple prior advanced therapies. There were also two non-NMSC malignancies reported in the 50 mg arm, both deemed unrelated to obefazimod by the study investigators. The results are summarized below.

Summary Safety Events, n (%)	Obefazimod 25 mg N=186	Obefazimod 50 mg N=447*
Any treatment-emergent adverse event (“TEAE”)	132 (71.0%)	307 (68.7%)
TEAE leading to study drug discontinuation	21 (11.3%)	27 (6.0%)
Serious TEAE	16 (8.6%)	23 (5.1%)
Death (Non-Treatment Related) ⁽¹⁾	1 (0.5%)	0
Pregnancy ⁽²⁾	1 (0.5%)	1 (0.2%)
Serious/severe (Grade ≥3) infections and opportunistic infections ⁽³⁾	5 (2.7%)	5 (1.1%)
Malignancies (excluding NMSC) ⁽⁴⁾	0	2 (0.4%)
NMSC ⁽⁵⁾	2 (1.1%)	2 (0.4%)
Acute pancreatitis	1 (0.5%)	1 (0.2%)
Cardiac abnormalities suggestive of cardiac fibrosis	0	0

(1) One death occurred in the 25 mg arm and was assessed by the investigator as unrelated to obefazimod. The suspected cause was pulmonary embolism in a 65+ patient with multiple pre-existing thromboembolic risk factors, including prior pulmonary embolism, and recent prolonged immobility.

(2) Both pregnancies are currently ongoing.

(3) Serious/severe (grade ≥3) infections and opportunistic infections: 25 mg = Appendicitis, Bartonellosis, Cytomegalovirus gastrointestinal infection, Peritonsillar abscess, Sepsis; 50 mg (induction non-responder) = Clostridium difficile infection, pilonidal disease, Urethritis gonococcal; 50 mg Open Label (Part 1 relapsers = Appendicitis (Part 1 50 mg), Septic arthritis staphylococcal (Part 1 placebo).

(4) Part 1 relapsers previous on placebo: One case of Myoproliferative Neoplasm and one Prostate Cancer.

(5) Two cases of Basal Cell Carcinoma (25 mg | 50 mg) and two cases of Squamous Cell Carcinoma (25 mg | 50 mg).

* Includes combined induction non-responders on 50 mg in Part 2 (N=251) and Part 1 relapsers (N=196) who entered Part 2.

	Malignancy (Excluding NMSC)	Exposure to Obefazimod	Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Cancer	Summary
50 mg	Myeloproliferative Neoplasm (MPN)	7.4 months	40+	No	2 (adalimumab, infliximab)	mesalazine	No	Thrombocythemia since 2023. Had elevated platelets at baseline (909,000 per microliter) Determined not related to study drug by investigator
	Prostate Cancer	3.4 months	55+	Yes azathioprine	2 (infliximab, vedolizumab)	prednisolone, mesalazine, budesonide	No	Limited adenocarcinoma of the prostate CT2 CN0 M0; Gleason score 7B Determined not related to study drug by investigator

	NMSC	Exposure to Obefazimod	Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Skin Cancer	Summary
50 mg	Basal Cell Carcinoma	10.4 months	40+	Yes azathioprine	3 vedolizumab, infliximab, ustekinumab	mesalazine, prednisone	No	Thiopurine use and failure of 3 prior advanced therapies Determined probably related to study drug by investigator
	Squamous Cell Carcinoma	4.6 months	55+	Yes azathioprine	2 adalimumab, vedolizumab	budesonide	Yes	Prior history of squamous cell carcinoma and history of multiple skin lesions Determined not related to study drug by investigator
25 mg	Basal Cell Carcinoma	8.1 months	50+	Yes azathioprine	None	budesonide, sulfasalazine, mesalazine, prednisone, metranidazole, sodium butyrate	No	Age 50+, prior thiopurine history Determined unlikely related to study drug by investigator
	Squamous Cell Carcinoma	8.3 months	75+	No	2 adalimumab, vedolizumab	prednisone, mesalamine	Yes	Age 75+ and prior history of 2x Basal cell carcinoma Determined probably related to study drug by investigator

The post-hoc analyses below are presented progressively, from the combined Phase 2 and Phase 3 UC programs to the Phase 3 maintenance dataset (Part 1 and Part 2), and then to the Part 2 maintenance dataset, to illustrate how increasing cumulative patient-years (“PYs”) strengthens the overall safety assessment. Because NMSCs and malignancies excluding NMSCs are uncommon events, incidence-rate estimates become more precise as cumulative exposure increases. The Company believes the Phase 3 maintenance data should be interpreted using the totality of the exposure-adjusted evidence, together with patient characteristics and representative published UC epidemiologic reference

ranges. The results in the tables below demonstrate that the exposure-adjusted incidence rate (“EAIR”) in the combined all active (25 mg and 50 mg) treatment arms for both NMSCs and malignancies excluding NMSCs are within the UC background reference range based on published UC studies.

Malignancies (Excluding NMSC) – EAIR Analysis					
Analysis Set	Placebo IR/100 PY	25 mg IR/100 PY	50 mg IR/100 PY	All Active IR/100 PY	Reference Range Based on Published UC Studies
Integrated UC Program (Phase 2 + Phase 3)	0.00	0.00	0.64	0.35	0.30 – 0.70
Phase 3 Maintenance (Part 1 + Part 2)	0.00	0.00	0.91	0.56	0.30 – 0.70
Part 2 Only	—	0.00	0.69	0.48	0.30 – 0.70

Note: IR = incidence rate

NMSC – EAIR Analysis					
Analysis Set	Placebo IR/100 PY	25 mg IR/100 PY	50 mg IR/100 PY	All Active IR/100 PY	Reference Range Based on Published UC Studies
Integrated UC Program (Phase 2 + Phase 3)	0.46	0.53	0.64	0.59	0.70 – 1.40
Phase 3 Maintenance (Part 1 + Part 2)	0.68	1.09	1.37	1.26	0.70 – 1.40
Part 2 Only	—	1.52	0.69	0.95	0.70 – 1.40

Note: IR = incidence rate

The overall safety results observed in Part 2 were consistent with those previously observed in the broader obefazimod clinical development program. No new safety pattern emerged with the additional cumulative exposure provided by Part 2.

Regulatory Path Forward

The Company believes the foregoing Part 2 results expand the integrated clinical dataset supporting the planned New Drug Application (“NDA”) for obefazimod in UC. The Company believes it remains on track to submit its NDA to the U.S. Food and Drug Administration in the fourth quarter of 2026.

Next Anticipated Key Milestones

- September 21, 2026 – Half-year 2026 financial results
- Fourth Quarter 2026 – Planned NDA submission for obefazimod in UC
- Mid-2027 – Topline results from the Phase 2b ENHANCE-CD induction trial evaluating obefazimod in Crohn’s disease

Press Release

A copy of the press release announcing the foregoing results is furnished as Exhibit 99.1 to this Report on Form 6-K.

Incorporation by Reference

This Report on Form 6-K, excluding Exhibit 99.1, shall be deemed to be incorporated by reference into the Registrant’s registration statements on Form F-3 (File Nos. 333-283336 and 333-288884) and Form S-8 (File Nos. 333-286069 and 333-294544) and to be part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed.

Exhibit Index

Exhibit 99.1 [Press Release, dated June 29, 2026](#)

Forward-Looking Statements

This Report on Form 6-K contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "expect," "intend," "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 obefazimod's potential to redefine treatment expectations, the expected timing for completion of the Phase 2b ENHANCE-CD induction trial of obefazimod and the availability and timing of results therefrom, the timing of regulatory filings including an NDA submission for obefazimod in UC, the timing for reporting Abivax's half year 2026 financial results, and other statements that are not historical fact. Although the Registrant'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 the Registrant, 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 23, 2026 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 Report. Readers are cautioned not to place undue reliance on these forward-looking statements. The Registrant 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 Report is not intended to constitute an advertisement. This Report 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Abivax SA
(Registrant)

Date: June 29, 2026

/s/ Marc de Garidel

Marc de Garidel
Chief Executive Officer



Abivax Reports Positive ABTECT Maintenance Part 2 Results for Obefazimod, Demonstrating Meaningful Clinical Benefit in Refractory Ulcerative Colitis Patients and Strengthening the Phase 3 Maintenance Safety Database

- *Obefazimod delivered meaningful clinical benefit in a highly refractory ulcerative colitis ("UC") population, with 37.2% of induction non-responders achieving clinical remission and 34.5% achieving endoscopic remission at Week 44 following continued 50 mg treatment*
- *Dose escalation to obefazimod 50 mg recaptured clinical remission in 45.5% of patients who relapsed during ABTECT Maintenance Part 1, supporting a practical dose-escalation strategy for regaining and sustaining disease control over time*
- *Across the integrated Phase 2 and Phase 3 UC program (1,704 patient-years of exposure), exposure-adjusted incidence rates ("EAIRs") for malignancies excluding non-melanoma skin cancer ("NMSC") were 0.35 and 0.64 events per 100 patient-years ("PYs"), and for NMSC were 0.59 and 0.64 events per 100 PYs in the all-active combined (50 mg + 25 mg) and 50 mg cohorts, respectively, all consistent with expected UC background rates*
- *In ABTECT Maintenance Part 2, EAIRs for malignancies excluding NMSC were 0.48 and 0.69 events per 100 PYs, and for NMSC were 0.95 and 0.69 events per 100 PYs, in the all-active combined and 50 mg cohorts, respectively, all consistent with expected UC background rates*
- *Abivax to host a conference call and webcast today at 4:30 p.m. EDT (10:30 p.m. CEST) to discuss the results*

PARIS, France – June 29, 2026 – 10:05 pm CEST – [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 topline results from ABTECT Maintenance Part 2, the supplemental portion of its Phase 3 UC maintenance program evaluating obefazimod, its investigational oral miR-124 enhancer, in adults with moderately to severely active UC.

Part 2 of the Phase 3 Maintenance trial enrolled patients who either did not achieve clinical response following induction treatment or who experienced disease relapse during the re-randomized maintenance trial (Part 1), expanding both the efficacy and safety results in a more refractory patient population than the registrational maintenance cohort.

The additional safety results generated through Part 2 expand the Phase 3 maintenance database and provide important context for interpreting the safety findings reported following the Maintenance Part 1 readout. The integrated post-hoc analyses presented today include the new Part 2 results, the combined Phase 3 maintenance program, and the broader Phase 2 and Phase 3 clinical development program.

Marc de Garidel, MBA, Chief Executive Officer of Abivax, said: *"The results from ABTECT Maintenance Part 2 represent an important milestone in the clinical development of obefazimod, demonstrating meaningful clinical benefit in patients with highly refractory ulcerative colitis while substantially expanding our long-term safety database. Together with the unprecedented efficacy results from the ABTECT Phase 3 program, these findings build a comprehensive body of evidence supporting the potential of obefazimod to address significant unmet needs across a broad spectrum of patients living with ulcerative colitis."*

"The expanded cumulative safety data further strengthens our confidence in the long-term safety profile of obefazimod and reinforces the favorable benefit-risk profile for our program as we prepare for our planned NDA submission later this year. We believe this growing body of evidence positions obefazimod, if approved, to become a paradigm defining treatment option for patients living with ulcerative colitis."

Clinically meaningful efficacy results observed in induction non-responders following additional obefazimod exposure

Among patients who failed to achieve clinical response after 8 weeks of induction, continued treatment with obefazimod resulted in clinically meaningful rates of clinical, endoscopic, and combined histologic-endoscopic endpoints at Week 44. Patients treated continuously with 50 mg obefazimod demonstrated the strongest outcomes across all endpoints, including clinical remission (37.2%), clinical response (61.5%), endoscopic improvement (48.0%), Histologic-Endoscopic Mucosal Improvement ("HEMI") (44.6%), and endoscopic remission (34.5%). These findings suggest that a meaningful proportion of patients who do not initially respond may still derive substantial benefit from longer treatment exposure.

Part 2 Induction Non-Responders – Exploratory Endpoints		
	25 mg (N=81)	50 mg (N=148)
Clinical Remission	23.5%	37.2%
Clinical Response	50.6%	61.5%
Endoscopic Improvement	28.4%	48.0%
HEMI	23.5%	44.6%
Endoscopic Remission	22.2%	34.5%

Obefazimod recaptured clinical and endoscopic outcomes in patients who relapsed during maintenance treatment

Among patients who relapsed during Maintenance Part 1, re-treatment with 50 mg obefazimod resulted in clinically meaningful rates of clinical remission, clinical response, endoscopic improvement, HEMI and endoscopic remission by Week 44. Patients who achieved clinical response with obefazimod during induction and relapsed after being re-randomized to placebo in Part 1 of the maintenance trial were treated with open-label 50 mg obefazimod and achieved clinical response and remission rates of 69.7% and 45.0%, respectively, while patients who relapsed on 25 mg and escalated to 50 mg achieved clinical response and remission rates of 66.7% and 45.5%, respectively. These findings demonstrate the potential for obefazimod to re-establish disease control following relapse and support a flexible maintenance treatment strategy.

Part 1 Relapsers – Exploratory Endpoints		
	Placebo->50 mg (N=109)	25 mg->50 mg (N=33)
	50 mg	50 mg
Clinical Remission	45.0%	45.5%
Clinical Response	69.7%	66.7%
Endoscopic Improvement	54.1%	45.5%
HEMI	47.7%	39.4%
Endoscopic Remission	32.1%	24.2%

Part 2 meaningfully expanded the cumulative safety dataset, increasing confidence in obefazimod’s long-term safety profile

The post-hoc analyses below are presented progressively, from the combined Phase 2 and Phase 3 UC programs to the Phase 3 maintenance dataset (Part 1 + Part 2), and then to the Part 2 maintenance dataset, to illustrate how increasing cumulative patient-years strengthens the overall safety assessment. In Part 2, four total NMSC events were reported, two in the 25 mg arm and two in the 50 mg arm, which all occurred in patients with established NMSC risk factors including advanced age, thiopurine use, prior skin cancer history and failure of multiple prior advanced therapies. There were also two non-NMSC malignancies reported in the 50 mg arm, both deemed unrelated to obefazimod by the study investigators.

Because NMSCs and malignancies excluding NMSCs are uncommon events, incidence-rate estimates become more precise as cumulative exposure increases. The ABTECT Maintenance data should be interpreted using the totality of the exposure-adjusted evidence, together with patient characteristics and representative published UC epidemiologic reference ranges. The results in the tables below demonstrate that the exposure-adjusted incidence rate in the combined all active (25 mg + 50 mg) treatment arms for both NMSCs and malignancies excluding NMSCs are within the UC background reference range based on published UC studies.

Malignancies (Excluding NMSC) – EAIR Analysis

Analysis Set	Placebo IR/100 PY	25 mg IR/100 PY	50 mg IR/100 PY	All Active IR/100 PY	Expected UC Background ¹
Integrated UC Program (Phase 2 + Phase 3)	0.00	0.00	0.64	0.35	0.30 – 0.70
Phase 3 Maintenance (Part 1 + Part 2)	0.00	0.00	0.91	0.56	0.30 – 0.70
Part 2 Only	–	0.00	0.69	0.48	0.30 – 0.70

NMSC – EAIR Analysis

Analysis Set	Placebo IR/100 PY	25 mg IR/100 PY	50 mg IR/100 PY	All Active IR/100 PY	Expected UC Background ²
Integrated UC Program (Phase 2 + Phase 3)	0.46	0.53	0.64	0.59	0.70 – 1.40
Phase 3 Maintenance (Part 1 + Part 2)	0.68	1.09	1.37	1.26	0.70 – 1.40
Part 2 Only	–	1.52	0.69	0.95	0.70 – 1.40

Part 2 strengthened confidence in obehazimod’s benefit-risk profile ahead of NDA submission

The overall safety results observed in Part 2 were consistent with those previously observed in the broader obehazimod clinical development program. No new safety pattern emerged with the additional cumulative exposure provided by Part 2.

Detailed exposure-adjusted analyses by trial, dose, cumulative patient-years, and patient characteristics will be presented during today’s investor webcast.

Remo Pannacione, M.D., Professor of Medicine and Director of the IBD Clinic at the University of Calgary stated: *“The ABTECT Maintenance Trial delivered compelling evidence supporting the clinical potential of obehazimod in ulcerative colitis. The robust efficacy results observed in both induction responders (Part 1) and induction non-responders (Part 2) demonstrate a consistent treatment effect across clinically important patient populations, while the expanding long-term safety dataset continues to provide reassurance, with observed rates of malignancies and non-melanoma skin cancers remaining consistent with expected background rates in ulcerative colitis. Collectively, these findings support a highly favorable benefit-risk profile and strengthen my confidence that obehazimod, if approved, has the potential to become an important new therapeutic option with the ability to meaningfully impact the treatment paradigm for patients with ulcerative colitis.”*



Today's Investor Webcast

Abivax management will host a webcast and conference call today at 4:30 p.m. EDT (10:30 p.m. CEST) to discuss the ABTECT Maintenance Part 2 results. To participate, please use the following dial-in or webcast link: <https://edge.media-server.com/mmc/p/o5thz2vd>

Regulatory Path Forward

The ABTECT Maintenance Part 2 results expand the integrated clinical dataset supporting the planned New Drug Application ("NDA") for obehazimod in UC. The Company remains on track to submit its NDA to the U.S. Food and Drug Administration in the fourth quarter of 2026.

Next Anticipated Key Milestones

- September 21, 2026 – Half-year 2026 financial results
- Fourth Quarter 2026 – Planned NDA submission for obehazimod in UC
- Mid-2027 – Topline results from the Phase 2b ENHANCE-CD induction trial evaluating obehazimod in Crohn's disease

UC Background Incidence Rate Sources

1. Long et al. *Gastroenterology*. 2012; Bencardino et al. *Cancers (Basel)*. 2025; Beaugerie et al. *The Lancet*. 2009; Kaneko et al. *Journal of Clinical Medicine*. 2024, Lemaitre et al. *JAMA*. 2017, National Cancer Institute. *SEER Statistics*.
2. Long et al. *Gastroenterology*. 2012; Bencardino et al. *Cancers (Basel)*. 2025; Abbas et al. *American Journal of Gastroenterology*. 2014.

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, obehazimod (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

Media Contact:

LifeSci Communications

Karissa Baltz, Ph.D.
Associate Director
LSC_ABIVAX@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," "on track," "potential," "will" 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 obefazimod's potential to redefine treatment expectations, the expected timing for completion of the Phase 2b ENHANCE-CD induction trial of obefazimod and the availability and timing of results therefrom, the timing of regulatory filings including an NDA submission for obefazimod in UC, the timing for reporting Abivax's half year 2026 financial results, 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 its Annual Report on Form 20-F for the fiscal year ended December 31, 2025 filed with the U.S. Securities and Exchange Commission on March 23, 2026 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.