



## **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.

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

<b>Part 1 Relapsers – Exploratory Endpoints</b>		
	<b>Placebo-&gt;50 mg</b> (N=109)	<b>25 mg-&gt;50 mg</b> (N=33)
	<b>50 mg</b>	<b>50 mg</b>
<b>Clinical Remission</b>	45.0%	45.5%
<b>Clinical Response</b>	69.7%	66.7%
<b>Endoscopic Improvement</b>	54.1%	45.5%
<b>HEMI</b>	47.7%	39.4%
<b>Endoscopic Remission</b>	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 <sup>1</sup>
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 <sup>2</sup>
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 obefazimod’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 obefazimod 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 obefazimod 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 obefazimod, 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 obefazimod 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 obefazimod in UC
- Mid-2027 – Topline results from the Phase 2b ENHANCE-CD induction trial evaluating obefazimod 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, 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. 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.*