

Efficacy, Persistence, and Safety of Obefazimod in Patients With Moderately to Severely Active Ulcerative Colitis: 3-year Interim Analysis Following Dose De-escalation to 25 mg in the Open-label Maintenance Phase 2 Study

Bram Verstockt¹, Silvio Danese², Parambir S Dulai³, Laurent Peyrin-Biroulet⁴, Marla Dubinsky⁵, Herbert Tilg⁶, Britta Siegmund⁷, Geert D'Haens⁸, Raja Atreya⁹, David T Rubin¹⁰, Tadakazu Hisamatsu¹¹, Kevin Shan¹², Pascaline Ploncard¹², Doug Jacobstein¹², Fabio Cataldi¹², Christopher J Rabbat¹², Bruce E Sands⁵, Alessandro Armuzzi¹³

1: UZ Leuven, Leuven, Belgium, 2: IRCCS Ospedale San Raffaele, Italy, 3: Feinberg School of Medicine Northwestern University, Chicago, USA, 4: University of Lorraine, Nancy, France, 5: Icahn School of Medicine at Mount Sinai, New York, 6: Medical University Innsbruck, Austria, 7: Charité UniversitätsmedizinBerlin, Berlin, Germany, 8: Amsterdam University Medical Center, 9: University Hospital Erlangen, Erlangen, Germany, 10: University of Chicago Medicine, Chicago, USA, 11: Kyorin University School of Medicine, Tokyo, Japan, 12: Abivax, Paris, France, 13:IRCCS Humanitas Research Hospital, Milan, Italy

MP0294

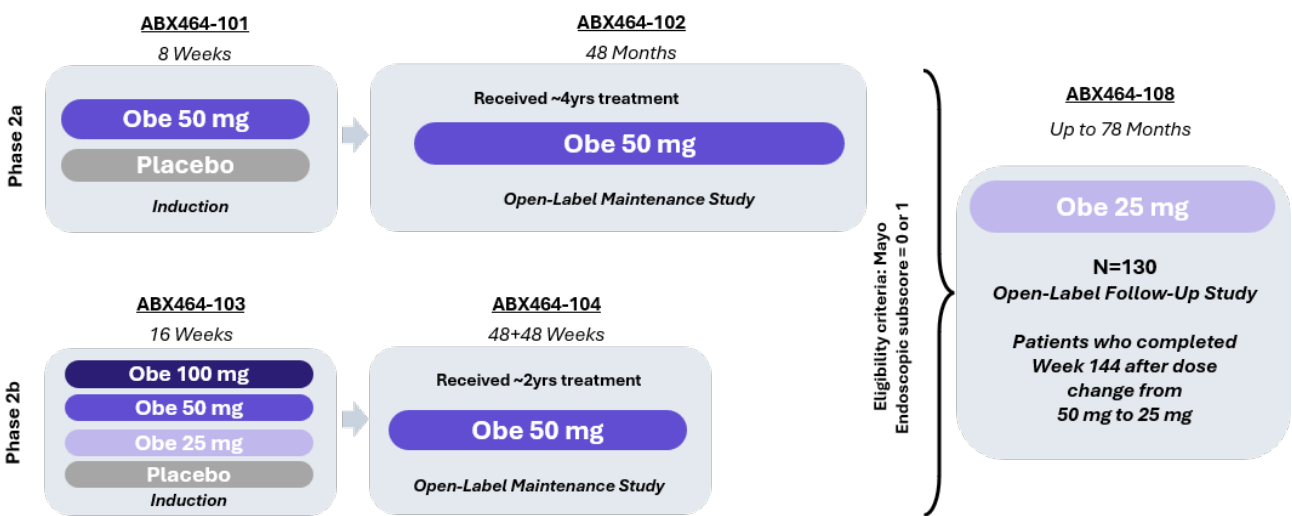
Introduction

- > **Obefazimod (Obe) is an oral, once-daily, small molecule that enhances the expression of microRNA-124, thereby restoring intestinal immune balance** through regulation of Th17 cells and macrophage activity
- > **Obe has shown efficacy in patients with moderately to severely active ulcerative colitis (UC)** in two Phase 2 induction trials and subsequent open-label maintenance (OLM) studies [1-3], as well as in the Phase 3 ABTECT induction and maintenance trials [4]

Methods

- > **Patients with UC received Obe 50 mg in the Phase 2 trials for 2 to 4 years**; those who achieved endoscopic improvement (Mayo Endoscopic subscore = 0 or 1 and rectal bleeding subscore = 0) were eligible to enroll in an OLM study (**Fig 1**)
- > Patients enrolled can **receive Obe 25 mg for up to an additional 78 months**
- > **This interim analysis (data transfer date: February 13, 2026) reports efficacy outcomes through the Week 144 visit** (clinical remission, endoscopic improvement, endoscopic remission, and symptomatic remission), **using both a non-responder imputation and as observed analysis**
- > Treatment emergent adverse events (TEAEs), serious TEAEs, and study discontinuation rates were examined

Study Design (Figure 1)



Results

Dosing and Patient Population

- > Patients with UC received Obe 50 mg for approximately four years in the Phase 2a OLM study and for approximately two years in the Phase 2b OLM study
 - Out of 174 pts who completed these studies (10 in Phase 2a OLM, 164 in Phase 2b OLM), 138 were eligible
- > Overall, **130 pts received treatment in the Obe-25 OLM**
 - Among this cohort, 16 pts (12%) discontinued prior to W48, including 4 who were subsequently found to be ineligible after enrollment
 - 7 pts (5%) discontinued between W48 and W96; and 3 pts (2%) discontinued between W96 and W144
 - As of the data transfer date, 113 pts (87%) completed the W48 visit, 107 (82%) the W96 visit and 104 (80%) the W144 visit

Clinical Remission

- > Following treatment with Obe-25, **rates of clinical remission were 73% at W48, 69% at W96 and 68% at W144, while symptomatic remission rates ranged from 72% to 79%** (NRI analysis)
- > In the as-observed analysis among Week 144 completers, **clinical remission rates were 84-85% through W144, while symptomatic remission rates ranged from 89% to 91%**. Consistent trends were observed across other efficacy endpoints (**Fig 2**)

Disease Activity

- > **Median fecal calprotectin (FCP) ranged from 48 to 98 µg/g over the 144-week study period**
- > Among pts with available FCP data at W144, 81% (72/89) had FCP levels <250 µg/g and 69% (61/89) had levels <150 µg/g (**Fig 3**)

Figure 2. Clinical, Symptomatic, and Endoscopic Endpoints Following Treatment With 25 mg

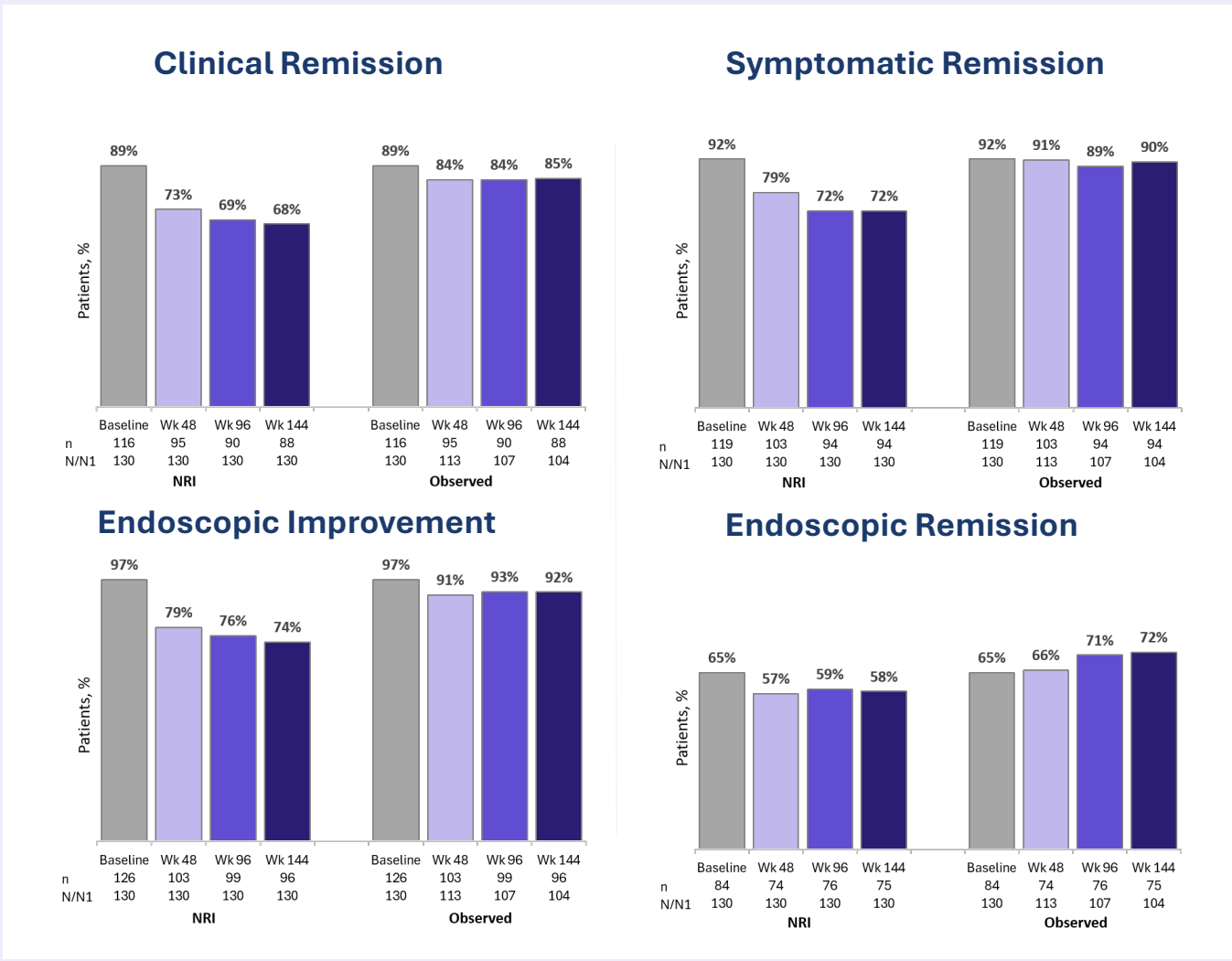
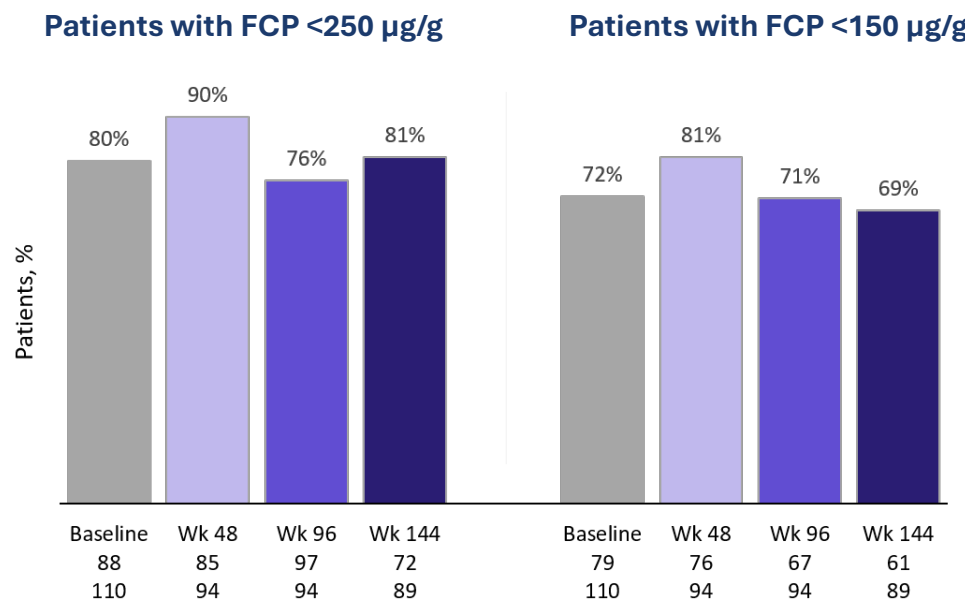


Figure 3. Patients With FCP <250 µg/g and <150 µg/g Following Treatment With 25 mg



Author's Conclusions

- > **After 2-4 years of open-label treatment with Obe-50, a high proportion of pts maintained efficacy across clinical, endoscopic, and symptomatic endpoints, and biomarkers of inflammation on Obe-25 for up to three additional years**
- > Across up to 7 years of treatment, no safety signal for infections or malignancies emerged—consistent with obefazimod's MOA of restoring intestinal immune balance while preserving key immune surveillance functions

Safety

- > **No safety signals were identified over the 144-week period (Table)**

	All Patients (N=130)	
	n (%)	IR/100 Pt Yrs
Any TEAE	96 (73.8)	87.9
Serious TEAE	8 (6.2)	3.9
Death	0	0
TEAE leading to discontinuation	9 (6.9)	4.3
Treatment Emergent Adverse Events (≥3% of patients)		
Ulcerative Colitis	15 (11.5)	7.3
Nasopharyngitis	11 (8.5)	5.4
Upper respiratory tract infection	10 (7.7)	4.9
COVID-19	11 (8.5)	5.4
Hypertension	7 (5.4)	3.4
Diarrhea	5 (3.8)	2.4
Arthralgia	5 (3.8)	2.4
Gastroenteritis	4 (3.1)	1.9
Opportunistic Infections	0	0
Non-melanoma skin cancer	1 (0.8)	0.5

IR: incidence rate, TEAE: treatment emergent adverse event
This table does not include laboratory findings

References

1. Vermeire S, et al. J Crohns Collitis. 2023;17:1689-1697; 2. Vermeire S, et al. Lancet Gastroenterol Hepatol. 2022;7:1024-1035; 3. Vermeire S, et al. J Crohns Collitis. 2025;19: jja074; 4. Sands BE, et al. UEG Journal, 2025; 13:1818-1820.

Disclosures

BV: Abbvie, Agomab, Alfasigma, Biogen, Biora Therapeutics, BMS, Celtrion, Eli Lilly, Falk, Ferring, Galapagos, Landos, Materia Prima, J&J, Pfizer, Sandoz, Sanofi, Sosei Heptares/Nxera, Takeda, Tillots Pharma, Truvion and Viatrix, Alimentiv, Anaptys Bio, Applied Strategic, Astrazeneca, Atheneum, BenevolentAI, Biora Therapeutics, Boxer Capital, BMS, Domain Therapeutics, Guidepoint, Landos, Merck, Mirador Therapeutics, Mylan, Nxera, Inotrem, Ipsos, Sanofi, Santa Ana Bio, Sapphire Therapeutics, Sosei Heptares, Thethis Pharma, Vagustim, Viatrix. SD: AbbVie, Celtrion, Ferring, Fresenius Kabi, Hospira, Johnson & Johnson, Medac, Merck, MSD, Takeda, Mundipharma, Pfizer Inc, Tigenix, UCB Pharma, Vifor, Biogen, Celgene, Allergan, Celtrion, Sandoz, Boehringer Ingelheim, PSD: Abbvie, Abivax, Adiso, Alimentiv, BMS, Celtrion, Fresenius Kabi, Genentech, Geneoscopy, Janssen, Pfizer, Takeda. LPB: Abbvie, Abivax, Adacety, Alimentiv, Amgen, Applied Molecular Transport, Arena, Banook, Biogen, BMS, Celtrion, Connect Biopharm, Cytokine Pharma, Enthera, Ferring, Fresenius Kabi, Galapagos, Genentech, Gilead, Gossamer Bio, GSK, IAC Image Analysis, Index Pharmaceuticals, Inotrem, Janssen, Lilly, Medac, Mopac, Morphic, MSD, Nordic Pharma, Novartis, Oncodesign Precision Medicine, ONO Pharma, OSE Immunotherapeutics, Pandion Therapeutics, Par Immune, Pfizer, Prometheus, Protagonist, Roche, Samsung, Sandoz, Sanofi, Satisfy, Takeda, Telavant, Theravance, Thermo Fischer, Tigenix, Tillots, Viatrix, Vectivbio, Ventyx, Ysopia. MD: Abbvie, Abivax, Arena Pharmaceuticals, Astra Zeneca, Boehringer Ingelheim International GmbH, BMS, Eli Lilly, F. Hoffmann-La Roche Ltd, Genentech Inc, Gilead, Janssen Pharmaceuticals, Merck, Pfizer Inc, Prometheus Biosciences, Takeda Pharmaceuticals. HT: Abbvie, Abivax, Dr Falk Pharma, ferring, Galapagos, Microbiotica, MSD, Pfizer, Takeda. BS: AbbVie, AltruBio, Abivax, AlfaSigma, BMS, Boehringer Ingelheim, CED Service GmbH, Dr. Falk Pharma, Eli Lilly, Endpoint Health, Falk, Ferring, Galapagos, Gilead, Janssen, Landos, Materia Prima, PredictImmune, MSD, Pfizer, Takeda, Tr1x bio. GDH: (consultant or speaker's fees) Abbvie, Abivax, Agomab, Alimentiv, Anaptys Bio, AstraZeneca, Bristol Meiers Squibb, Boehringer Ingelheim, Celtrion, Eli Lilly, Exeliom Biosciences, Galapagos, Glaxo Smith Kline, Dr Falk Pharma, Pfizer, J&J, Merck, Mirador, Polpharma, Precise Diagnostics, Prometheus Biosciences, Sorriso Pharma, Spyre, Takeda, Ventyx (Grant) Pfizer, BMS, J&J, Abbvie, Alimentiv BV, Eli Lilly, Takeda, Prometheus Laboratories. RA: AbbVie, Abivax, Adiso, Alimentiv, Bristol Meyer Squibb, Celtrion, Genentech, Geneoscopy, Janssen, Pfizer, Takeda. DTR: (consultant/speaker's fees) AbbVie, Abivax, AltruBio, Athos Therapeutics, Bristol-Myers Squibb, Celtrion, Connect BioPharma, Eli Lilly, Genentech, Iterative health, Janssen Pharmaceuticals, J&J, Merck, Odyssey Therapeutics, Pfizer, Sanofi, Spyre, Takeda, Vedanta Biosciences, Ventyx. TH: Abivax, AbbVie, BMS, Boston Scientific, EA Pharma, Eli Lilly, Gilead Sciences, Janssen, JPMO, Kissei, Kyorin, Mitsubishi Tanabe, Mochida, Nippon Kayaku, Pfizer, Takeda, Zenia. KS, PF, DJ, FC, and CR: Abivax. BES: Abbvie, Abivax, Adiso Therapeutics, Agomab, Alimentiv, Amgen, AnaptysBio, Arena Pharmaceuticals, Artugen Therapeutics, Astra Zeneca, Biologio Design, Biora Therapeutics, Boehringer Ingelheim, BMS, Celtrion, Equilium, Enthera, Enveda Biosciences, Evomune, Ferring, Fzata, Galapagos, Genentech, Gilead Sciences, GSK, Gossamer Bio, Imhotep, Index Pharmaceuticals, Innovation Pharmaceuticals, Kaleido, Kalyopeo, Lilly, Merck & Co., Microba, Microbiotica, Mitsubishi Tanabe, Mobius Care, Morphic Therapeutics, MRM Health, Nexus Therapeutics, Nimbus Discovery, Odyssey Therapeutics, OSE Immunotherapeutics, Janssen, Palisade Bio, Pfizer, Protagonist Therapeutics, Q32 Bio, Rassyana Therapeutics, Recludi Therapeutics, Relstone Biopharma, Sanofi, Sorriso Therapeutics, Spyre Therapeutics, Takeda, Target RWE, Teva, TLL Pharmaceutical, Tr1X, Trex Bio, Union Therapeutics, Ventyx Biosciences. AA: AbbVie, Abivax, AG Pharma, Alfa Sigma, Astra Zeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celtrion, Eli-Lilly, Enthera, Ferring, Galapagos, Gilead, Giuliani, Janssen, Lionhealt, MSD, Nestlé, Novartis, Pfizer, Protagonist Therapeutics, Roche, Samsung Bioipis, Sanofi, Sandoz, Takeda, Teva Pharmaceuticals, Tillots Pharma

ABIVAX

7-11 Blvd Haussmann- 75009 Paris, France
E-mail: info@abivax.com | abivax.com
Copyright © 2026 Abivax

Barcelona 2026

ueg week