



New composite outcomes data show patients treated with Lilly's Omvoh (mirikizumab-mrkz) achieved comprehensive corticosteroid-free disease control in ulcerative colitis and corticosteroid-free deep remission in Crohn's disease at one year

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In LUCENT-2, more than one in four (27.7%) Omvoh-treated patients with ulcerative colitis achieved comprehensive disease control, a novel composite outcome defined by simultaneous symptomatic, endoscopic and histologic remission, biomarker normalization and no corticosteroid use

In VIVID-1, one in five (20.4%) Omvoh-treated patients with Crohn's disease achieved corticosteroid-free deep remission, a composite outcome defined by simultaneous clinical remission, endoscopic remission and no corticosteroid use

Across both types of inflammatory bowel disease, including patients with prior biologic failure, achieving comprehensive disease control or corticosteroid-free deep remission was associated with improved patient-reported outcomes

INDIANAPOLIS, Oct. 15, 2026 /PRNewswire/ -- New data analyses from Eli Lilly and Company (NYSE: LLY) show patients with moderately to severely active ulcerative colitis (UC) and Crohn's disease treated with Omvoh (mirikizumab-mrkz) achieved multiple treatment goals simultaneously at one year, as measured by comprehensive disease control in UC and corticosteroid-free deep remission in Crohn's disease. These multidimensional outcomes were observed even in patients with prior biologic failure, a population often facing greater treatment challenges. More than one-third of patients in the UC analysis and nearly half of patients in the Crohn's disease analysis had previously experienced biologic treatment failure. Furthermore, patients who achieved these endpoints were more likely to also achieve remission on the Inflammatory Bowel Disease Questionnaire (IBDQ), a validated patient-reported measure of health-related quality of life. Together, these findings reflect an evolution of treatment goals in inflammatory bowel disease (IBD), looking across symptoms, inflammation and impact of disease on daily life to support a more holistic, patient-centered approach that goes beyond clinical remission. These post-hoc data from the LUCENT and VIVID programs will be presented at United European Gastroenterology (UEG) Week 2026.^{1,2}

"Treatment in inflammatory bowel disease is often measured one endpoint at a time. These new data show that patients treated with Omvoh achieved multiple treatment goals simultaneously at one year, including those with prior biologic failure, and were more likely to report better quality of life," said Anabela Cardoso, senior vice president, Lilly Immunology Medical Affairs. "These findings reinforce the impact that Omvoh can have for people living with ulcerative colitis and Crohn's disease and show that a higher bar for disease control is achievable."

A comprehensive approach to IBD management considers multiple dimensions of disease, including the symptoms patients experience, what clinicians can objectively measure and how disease affects daily life.³⁻⁴ In previously published real-world studies, improvements across multiple dimensions of disease have been associated with a lower risk of flares, steroid use, hospitalization and surgery over time.⁴⁻⁷

"Inflammatory bowel disease is complex, and understanding treatment impact requires a broader view than any single endpoint can provide. These endpoints reflect a meaningful shift in how we define treatment success," said Stefan Schreiber, M.D., University Hospital Schleswig-Holstein, Christian-Albrecht University of Kiel. "Across the LUCENT and VIVID programs, Omvoh-treated patients achieved multidimensional treatment outcomes, including comprehensive disease control in ulcerative colitis and corticosteroid-free deep remission in Crohn's disease. Importantly, these outcomes were also observed in patients with prior biologic failure."

Comprehensive disease control with Omvoh in ulcerative colitis

Comprehensive disease control is a novel composite outcome, informed by an international expert consensus³, that combines clinical remission*, no corticosteroid use for at least 12 weeks before Week 52, histologic remission[†] and fecal calprotectin ≤ 250 $\mu\text{g/g}$. Omvoh is the first IL-23p19 inhibitor evaluated for comprehensive disease control in UC, reflecting an evolving approach to treatment goals that goes beyond individual measures of disease activity for people living with UC.

Comprehensive disease control was evaluated in a post hoc analysis at one year in patients with UC who responded to Omvoh at Week 12 in the LUCENT-1 induction study and were re-randomized in LUCENT-2 to continue Omvoh or receive placebo. More than one-third of patients (35.3%) had previously experienced biologic treatment failure.

At one year:¹

- 27.7% of patients treated with Omvoh achieved comprehensive disease control compared with 14% receiving placebo.[‡]
- Among patients with prior biologic failure, 23.4% of those treated with Omvoh achieved comprehensive disease control compared with 9.4% receiving placebo.[‡]
- Among Omvoh-treated patients, 91.1% of those who achieved comprehensive disease control also achieved IBDQ remission[§], compared with 65.2% of those who did not achieve comprehensive disease control.
- Omvoh-treated patients who achieved comprehensive disease control were also more likely to report no to minimal bowel urgency (bowel urgency remission) and greater improvements in work productivity than those who did not achieve comprehensive disease control.^{||}

Corticosteroid-free deep remission with Omvoh in Crohn's disease

Corticosteroid-free deep remission was evaluated in a post hoc analysis at one year in patients with Crohn's disease in VIVID-1. Nearly half of patients (48.6%) had previously experienced biologic treatment failure. Corticosteroid-free deep remission is a composite outcome that combines clinical remission (as measured by the Crohn's Disease Activity Index), endoscopic remission and no corticosteroid use for at least 12 weeks before Week 52.[¶]

At one year:²

- 20.4% of patients receiving Omvoh achieved corticosteroid-free deep remission compared with 2% receiving placebo.[#]
- Among patients with prior biologic failure, 15.7% of those treated with Omvoh achieved corticosteroid-free deep remission compared with none of those receiving placebo.[#]
- Among Omvoh-treated patients, 88.1% of those who achieved corticosteroid-free deep remission also achieved IBDQ remission[§], compared with 51% of those who did not achieve corticosteroid-free deep remission.

The safety findings observed in the Phase 3 LUCENT and VIVID clinical trial programs have been reported previously. The most common adverse reactions associated with Omvoh treatment in LUCENT-1 and -2 (reported in at least 2% of subjects at a higher frequency than placebo) were upper respiratory tract infections, injection site reactions, arthralgia, rash, headache and herpes viral infection. In VIVID-1, the most common adverse reactions associated with Omvoh treatment (reported in at least 5% of subjects at a higher frequency than placebo) were upper respiratory tract infections, injection site reactions, headache, arthralgia and elevated liver tests.⁸

Omvoh has received regulatory approvals for the treatment of moderately to severely active UC and moderately to severely active Crohn's disease in adults and has been approved in 47 countries. Omvoh is also approved as a single-injection maintenance regimen for adults with UC in several countries around the world, including the U.S., EU, Canada and Japan.

Lilly continues to advance the standard of care in gastroenterology through the next wave of immunology innovation, including combination approaches, novel mechanisms and the potential of incretins. Lilly is pursuing combination studies of mirikizumab aimed at delivering breakthrough induction efficacy while maintaining long-term remission and safety. These include studies in UC with eltrekibart ([NCT06598943](#)), a monoclonal antibody that targets neutrophil-driven inflammation, and with zotemtegrast ([NCT07186101](#)), an oral $\alpha 4 \beta 7$ integrin inhibitor. In Crohn's disease, Lilly is studying mirikizumab in combination with an FXR agonist ([NCT07483099](#)). The COMMIT-UC ([NCT06937086](#)) and COMMIT-CD ([NCT06937099](#)) trials are investigating the concomitant use of mirikizumab and an incretin-based therapy in adults with UC or Crohn's disease and obesity or overweight with at least one additional weight-related comorbid condition. In addition, trials of mirikizumab in pediatric patients are ongoing, including a long-term extension study in UC and Crohn's disease ([NCT04844606](#)) and an ongoing Phase 3 study in pediatric Crohn's disease ([NCT05509777](#)).

About the LUCENT Clinical Trial Program

Omvoh was studied in two Phase 3 clinical trials which evaluated the efficacy and safety of Omvoh in adults with moderately to severely active UC, in both biologic-naïve patients and those who had previously failed a biologic or Janus kinase inhibitor (JAKi).

The randomized, double-blind, placebo-controlled LUCENT-1 (induction) study included patients with an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, biologic therapy, or JAKi, and LUCENT-2 (maintenance) evaluated continued treatment versus placebo in patients who achieved a clinical response to Omvoh in LUCENT-1.

About the VIVID Clinical Trial Program

VIVID-1 was a Phase 3 randomized, double-blind, placebo-controlled 52-week study in adults with moderately to severely active Crohn's disease. Patients randomized to Omvoh received Omvoh 900 mg by intravenous (IV) infusion at Week 0, Week 4 and Week 8, followed by a maintenance dose of 300 mg by subcutaneous injection (SC) at Week 12 and then every four weeks (Q4W) for 40 weeks.

About Omvoh

Omvoh (mirikizumab-mrkz) is an interleukin-23p19 (IL-23p19) antagonist indicated for the treatment of moderately to severely active ulcerative colitis and Crohn's disease in adults. Omvoh selectively targets the p19 subunit of IL-23 and inhibits the IL-23 pathway. Inflammation due to over-activation of the IL-23 pathway plays a critical role in the pathogenesis of inflammatory bowel disease.⁸

Omvoh and its delivery device base are trademarks owned by Eli Lilly and Company.

Endnotes and References

*Clinical remission (based on the modified Mayo score [mMS]): stool frequency subscore=0 or 1 with a ≥ 1 -point decrease from baseline, and rectal bleeding subscore=0, and endoscopic subscore (ES)=0 or 1 (excluding friability).

[†]Histologic remission: Geboes subscores of 0 for grades 2b (neutrophils in lamina propria), 3 (neutrophils in epithelium), 4 (crypt destruction) and 5 (erosion or ulceration).

[‡]In LUCENT-2, patients randomized to placebo had achieved clinical response with Omvoh during LUCENT-1 induction and were then re-randomized to discontinue from Omvoh and receive placebo through the maintenance period. Patients randomized to Omvoh continued treatment, for a total of 52 weeks from induction baseline.

[§]Inflammatory Bowel Disease Questionnaire (IBDQ) remission: total score ≥ 170 .

[¶]No to minimal bowel urgency (bowel urgency remission) was defined as an Urgency NRS score of 0 or 1; work productivity assessed using the Work Productivity and Activity Impairment Questionnaire for UC (WPAI).

^{¶¶}Corticosteroid-free Crohn's Disease Activity Index (CDAI)-based deep remission: CDAI < 150 , endoscopic remission (SES-CD ≤ 4 and ≥ 2 -point reduction from baseline with no subscore > 1) and no corticosteroid use during the 12 weeks before Week 52.

[#]Patients receiving placebo in VIVID-1 were randomized to placebo at baseline. Those who did not respond by Week 12 switched to Omvoh and were counted as non-responders in this analysis.

¹Schreiber S, et al. Mirikizumab therapy enables comprehensive disease control with improved quality of life in patients with moderately-to-severely active ulcerative colitis: a post-hoc analysis of Phase 3 LUCENT-1 and LUCENT-2 trials. American College of Gastroenterology (ACG) Annual

Scientific Meeting; October 11, 2026; Nashville, TN. P-1182.

²Schreiber S, et al. Mirikizumab effect on deep remission with improved quality of life in moderately to severely active Crohn's disease: a post hoc analysis from VIVID-1. United European Gastroenterology Week 2026; October 18, 2026; Barcelona, Spain. MP0290.

³Schreiber, S, Danese, S, Dignass, A, et al. Defining comprehensive disease control for use as a treatment target for ulcerative colitis in clinical practice: International Delphi consensus recommendations. *J Crohns Colitis*. 2024;18(1):91–105. <https://doi.org/10.1093/ecco-icc/ijad130>

⁴Fanizzi, F, D'Amico, F, Peyrin-Biroulet, L, Danese, S, & Dignass, A. Treatment targets in IBD: Is it time for new strategies? *Best Pract Res Clin Gastroenterol*. 2025;77:101990. <https://doi.org/10.1016/j.bpg.2025.101990>

⁵Shehab M, et al. Histological disease activity as predictor of clinical relapse, hospitalization, and surgery in inflammatory bowel disease: systematic review and meta-analysis. *Inflamm Bowel Dis*. 2024;30(4):563-572. doi:10.1093/ibd/izad119

⁶Andronic AM, Toader E. P398 Disease clearance: a potential target for management of patients with ulcerative colitis. *J Crohns Colitis*. 2023;17(Suppl 1):i529. doi:10.1093/ecco-icc/ijac190.0528

⁷Pai RK, D'Haens G, Kobayashi T, et al. Histologic assessments in ulcerative colitis: the evidence behind a new endpoint in clinical trials. *Expert Rev Gastroenterol Hepatol*. 2024;18(1-3):73-87. doi:10.1080/17474124.2024.2326838

⁸Omvoh. Prescribing Information. Lilly USA, LLC.

Indications and Usage for Omvoh® (mirikizumab-mrkz) (in the United States)

Omvoh is an interleukin-23 antagonist indicated for adults with:

- Moderately to severely active ulcerative colitis
- Moderately to severely active Crohn's disease

Important Safety Information for Omvoh (mirikizumab-mrkz)

CONTRAINDICATIONS

Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections

Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity

Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial subject following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS

Most common adverse reactions associated with Omvoh ($\geq 2\%$ of subjects and at a higher frequency than placebo) in ulcerative colitis treatment are upper respiratory tract infections and arthralgia during the induction study (UC-1), and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during the maintenance study (UC-2). Most common adverse reactions associated with Omvoh in the Crohn's disease study (CD-1) ($\geq 5\%$ of subjects and at a higher frequency than placebo) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Omvoh injection is available as a 300 mg/15 mL solution in a single-dose vial for intravenous infusion, and as a 100 mg/mL solution or a 200 mg/2 mL solution in a single dose prefilled pen or prefilled syringe for subcutaneous injection. Refer to the Prescribing Information for dosing information.

Click to access provided [Prescribing Information](#) and [Medication Guide](#). See Instructions for Use provided with the device.

About Lilly

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Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Omvoh (mirikizumab-mrkz) as a treatment for people with moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development and commercialization. Among other things, there is no guarantee that future study results will be consistent with the results to date, or that Lilly will execute its strategies as planned. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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