Lilly's Omvoh (mirikizumab-mrkz) is the first and only IL-23p19 to demonstrate durable disease clearance in ulcerative colitis through four years

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In LUCENT-3, more than 60% of patients who achieved disease clearance at one year maintained it after four years of continuous Omvoh treatment

Disease clearance is a high clinical bar in UC requiring simultaneous symptomatic, endoscopic and histologic remission

INDIANAPOLIS, May 5, 2026 /PRNewswire/ -- New long-term data from Eli Lilly and Company (NYSE: LLY) show patients with moderately to severely active ulcerative colitis (UC) treated with Omvoh (mirikizumab-mrkz) achieved durable disease clearance through four years of continuous treatment. In the LUCENT-3 open-label extension study, 63.5% of Omvoh-treated patients who achieved disease clearance at one year sustained it at four years. These results will be presented at Digestive Disease Week® (DDW) and represent the first time an interleukin-23p19 (IL-23p19) inhibitor has demonstrated durable disease clearance through four years in people with UC.[1]

Disease clearance is the simultaneous achievement of symptomatic, endoscopic and histologic remission. In real-world studies, achieving disease clearance has been associated with reduced rates of hospitalizations and surgery.[2-3] While previously reported four-year Omvoh data showed durable individual outcomes, this new analysis goes further by evaluating those outcomes together as a composite endpoint, reflecting a higher clinical bar.

"Ulcerative colitis is a lifelong disease, and every person living with the condition deserves a treatment that can deliver strong and durable disease control, not just symptom relief," said Adrienne Brown, executive vice president and president of Lilly Immunology. "Disease clearance sets that bar higher, and these data show Omvoh-treated patients achieved and sustained it over four years with consistent monthly dosing."

Durable Disease Clearance in Ulcerative Colitis
Disease clearance was evaluated among patients who achieved clinical remission with Omvoh at one year in the LUCENT-2 maintenance study and continued treatment in LUCENT-3, an open-label extension study. This analysis, which was not pre-specified, showed 63.5% of Omvoh-treated patients who achieved disease clearance at one year sustained it at four years.* Even at the most stringent measure — requiring endoscopic normalization in addition to symptomatic and histologic remission — 61.3% of patients who achieved it at one year maintained it through four years†.

"What makes these data so compelling is that they go beyond individual measures of improvement to show that patients treated with Omvoh achieved disease clearance, with simultaneous symptomatic, endoscopic and histologic remission, maintained over four years," said Jean-Frédéric Colombel, M.D., director of the Susan and Leonard Feinstein Inflammatory Bowel Disease Clinical Center at the Icahn School of Medicine at Mount Sinai. "Until now, disease clearance has not been demonstrated for this length of time for any IL-23p19 therapy in ulcerative colitis. For a progressive disease like ulcerative colitis, that level of durable remission has the potential to change the long-term course of the disease for patients."

These findings expand the growing body of long-term data on Omvoh in inflammatory bowel disease (IBD), building on previously disclosed four-year results in UC and three-year results in Crohn's disease, including reduction of serious disease-related complications. In LUCENT-3, one UC-related hospitalization and zero UC-related surgeries were reported by patients treated with Omvoh during the three-year long-term extension.[4]

The long-term safety profile in patients with moderately to severely active UC was consistent with the known safety profile of Omvoh with no new safety signals observed. Of patients who completed one year of blinded Omvoh maintenance therapy in LUCENT-2 and continued on to LUCENT-3, 12% reported a serious adverse event, while 7% discontinued treatment due to an adverse event.[5] The most common adverse reactions (reported in at least 2% of subjects at a higher frequency than placebo) associated with Omvoh treatment in LUCENT-1 and -2 were upper respiratory tract infections, injection site reactions, arthralgia, rash, headache and herpes viral infection.[6]

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. In UC, Lilly is pursuing combination studies of mirikizumab aimed at delivering breakthrough induction efficacy while maintaining long-term remission and safety. These include studies with eltrekibart (NCT06598943), a monoclonal antibody that targets neutrophil-driven inflammation, and with zotemtegrast (NCT07186101), an oral α4β7 integrin inhibitor. 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 in UC (NCT05784246) and Crohn's disease (NCT05509777).

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 around the world. In the U.S., Omvoh is also approved for a single-injection maintenance regimen in UC.

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.[5]

LUCENT-3, the single-arm long-term Phase 3 open-label extension of LUCENT-1 and LUCENT-2, evaluated the efficacy and safety of Omvoh in

patients with UC for an additional three years of treatment (up to four years total).

Using a modified non-responder imputation analysis to handle discontinuation and missing data, 49.7% and 42.8% of patients who achieved disease clearance and stringent disease clearance at one year, respectively, sustained it at four years.[1]

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.[6]

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

Endnotes and References
*Observed cases, post hoc. Symptomatic remission [Mayo stool frequency (SF)=0, or SF=1 with a ≥1-point decrease from baseline, and rectal bleeding=0], and histologic-endoscopic mucosal remission [Histologic remission (Geboes score ≤2B.0) and endoscopic remission (endoscopic subscore [ES] of 0 or 1, excluding friability)].
†Observed cases, post hoc. Symptomatic + histologic remission + endoscopic normalization (ES=0).
[1]Magro F, et al. Mirikizumab demonstrates consistent and sustained disease clearance at four years of treatment in patients with moderately to severely active ulcerative colitis. Digestive Disease Week 2026. May 2-5, 2026.
[2]Andronic AM, et al. *J Crohn's Colitis*. 2023;17(Supplement_1):i529. https://doi.org/10.1093/ecco-jcc/jjac190.0528
[3]Pai RK, et al. *Expert Rev Gastroenterol Hepatol*. 2024;18(1-3):73–87. https://doi.org/10.1080/17474124.2024.2326838
[4]Magro F, et al. *J Crohn's Colitis*. 2026;20(Suppl 1):jjaf231.1300. https://doi.org/10.1093/ecco-jcc/jjaf231.1300
[5]Sands, B, et al. Mirikizumab provides sustained long-term efficacy up to 4 years of treatment for ulcerative colitis: final results from the LUCENT-3 open-label extension study. 2025 United European Gastroenterology Week. October 4-7, 2025.
[6]Omvoh. 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 (≥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) (≥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.

MR HCP ISI CD APP

Click to access provided Prescribing Information and Medication Guide. See Instructions for Use provided with the device.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

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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 moderate to severe ulcerative colitis and moderate to severe 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 planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that Omvoh will receive additional regulatory approvals, or that Omvoh will be commercially successful. 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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