# Patients with Crohn's disease maintained steroid-free remission for three years with Lilly's Omvoh (mirikizumab-mrkz)

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*Landmark VIVID-2 data showed more than 90% of patients who achieved steroid-free remission at one year maintained steroid-free control through three years*

*Additional new data revealed exceptionally low surgery and hospitalization rates in Omvoh-treated patients across both Crohn's disease and ulcerative colitis (UC), underscoring its potential to fundamentally change disease trajectory*

*Omvoh now stands alone as the only IL-23p19 inhibitor to show strong and durable efficacy with simple, consistent monthly dosing over four years in UC and three years in Crohn's disease*

INDIANAPOLIS, Feb. 19, 2026 /PRNewswire/ -- New long-term data from Eli Lilly and Company (NYSE: LLY) showed Omvoh (mirikizumab-mrkz) delivered durable efficacy through three years in adults with moderately to severely active Crohn's disease.[1] These data from the Phase 3 VIVID-2 open-label extension study were presented at the 21st Congress of the European Crohn's and Colitis Organisation (ECCO) in Stockholm. Additional data presented from the Phase 3 VIVID-1 (Crohn's disease) and LUCENT-3 (UC) clinical trials showed Omvoh-treated patients experienced minimal hospitalizations and surgeries across both major types of inflammatory bowel disease (IBD).[2,3] Omvoh is the first and only IL-23p19 inhibitor to show strong and durable efficacy over four years in UC and three years in Crohn's disease, with proven reduction of disease complications.

"Too many people with inflammatory bowel disease never achieve lasting remission, leaving them vulnerable to cumulative damage from poorly controlled inflammation that can result in emergency hospitalizations or surgery," said Adrienne Brown, executive vice president and president of Lilly Immunology. "Omvoh is redefining what durable disease control can look like, with long-term data showing patients treated with Omvoh stayed in remission and experienced fewer serious complications over three years, underscoring its potential to alter the course of the disease."

*Long-Term Remission and Bowel Urgency Improvements in Crohn's Disease*

In VIVID-2, patients who achieved an endoscopic response at one year with Omvoh in the Phase 3 VIVID-1 clinical trial experienced long-term efficacy, with the majority remaining in clinical and corticosteroid-free remission and sustaining bowel urgency improvements through three years of continuous Omvoh treatment.[1]

| **Efficacy results at 152 weeks*** | |
|---|---|
| Clinical remission† | 92.4 % |
| Corticosteroid-free clinical remission‡ | 91.2 % |
| ≥3-point reduction on the Urgency Numeric Rating Scale (UNRS)§ | 82.1 % |
| UNRS ≤2¶ | 71.7 % |

** Among patients who achieved each specified outcome at Week 52 in VIVID-1 and continued treatment in the VIVID-2 extension; observed cases. These data were also evaluated using a modified non-responder imputation (mNRI), presented in the About VIVID Clinical Trial Program section below.*

*† Crohn's Disease Activity Index (CDAI) total score <150.*

*‡ CDAI score <150 with no corticosteroid use for prior 12 weeks.*

*§ UNRS is the patient-centric scale of 0-10 that evaluates bowel urgency severity, with 0 being no bowel urgency and 10 being worst possible bowel urgency.*

*¶ Among patients with baseline UNRS ≥3.*

"For people with Crohn's disease, unpredictable flares and abdominal pain can persist when remission isn't achieved or sustained. Additionally, ongoing symptoms like urgent trips to the bathroom and fatigue can continue to disrupt daily life when the disease is not adequately controlled," said Edward Barnes, M.D. MPH, Associate Professor of Medicine, University of North Carolina at Chapel Hill. "Seeing more than 90% of patients maintain steroid-free remission through three years on consistent monthly dosing, with 80% also experiencing relief from the disruptive symptoms of bowel urgency, gives providers confidence in Omvoh for outcomes that can last."

These new long-term Crohn's disease data also showed Omvoh-treated patients who achieved endoscopic response at one year experienced sustained improvement in inflammation, as measured by the continued decrease in inflammatory biomarkers (C-reactive protein and fecal calprotectin) up to three years.[1] The long-term safety profile in patients with moderately to severely active Crohn's disease was consistent with the known safety profile of Omvoh. Common adverse events reported from the end of year one through the end of year three (≥5% of Omvoh-treated patients who achieved endoscopic response at one year) included COVID-19, nasopharyngitis, and upper respiratory tract infection.[1]

*Consistently Low Rates of Severe Disease-Related Complications in IBD*

Complementing the three-year Crohn's disease results, additional post hoc data presented from the VIVID-1 (Crohn's disease) and LUCENT-3 (UC) clinical trials showed patients treated with Omvoh experienced consistently low rates of severe disease-related complications. In VIVID-1, Omvoh reduced Crohn's disease-related hospitalizations and/or surgeries by nearly half versus placebo in the first 12 weeks (incidence rate: 16.9 vs. 30.9 per

100 patient-years), and by nearly 70% during weeks 12 to 52 (4.5 vs. 14.0*).[2] In LUCENT-3, one UC-related hospitalization and no UC-related surgeries were reported by patients treated with Omvoh during the three-year long-term extension (incidence rates 0.1 and 0 per 100 patient-years, respectively).[3]

* Placebo rates during weeks 12 to 52 only include placebo patients who were in clinical response at week 12.

Together, these findings expand the growing body of long-term data on Omvoh in IBD, building on previously disclosed two-year results in Crohn's disease and four-year results in UC.

Lilly is advancing 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 LY4268989 (MORF-057) (NCT07186101), an oral α4β7 integrin inhibitor. Lilly is also advancing novel science to uncover the potential of incretins in immunology and has initiated the COMMIT-UC (NCT06937086) and COMMIT-CD (NCT06937099) trials evaluating the efficacy and safety of mirikizumab used concomitantly with an incretin-based therapy in adults with ulcerative colitis or Crohn's disease who also have obesity or are overweight with at least one weight-related comorbidity. 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.

**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 900mg by intravenous (IV) infusion at Week 0, Week 4 and Week 8 followed by a maintenance dose of 300mg by subcutaneous injection (SC) at Week 12 and then every 4 weeks (Q4W) for 40 weeks.[4]

Participants who completed VIVID-1, including the Week 52 endoscopy, were eligible for VIVID-2. In VIVID-2, the primary objective is to evaluate the long-term effect of Omvoh in clinical remission by CDAI and endoscopic response at Week 52 of treatment in VIVID-2 (totaling 104 weeks of continuous treatment). Safety is being assessed from the first dose in VIVID-2.[1]

Using a modified non-responder imputation method, among Omvoh endoscopic responders at year one, 82.8% of patients maintained CDAI clinical remission through three years, 81.1% maintained corticosteroid-free clinical remission, 72.7% maintained clinically meaningful improvement in bowel urgency and 64.0% of patients maintained bowel urgency remission.[1]

**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 biologic or Janus kinase inhibitors (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).

**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]



**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



**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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