



Lilly's Omvoh (mirikizumab-mrkz) meets primary endpoint of clinical remission and is the first IL-23p19 inhibitor to report one-year Phase 3 results in pediatric ulcerative colitis

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Building on Omvoh's approved use and durable efficacy in adults, Lilly plans to submit these data to global regulators to support a potential label expansion for pediatric ulcerative colitis

More than 80% of patients responded to Omvoh induction, and half of responders, ages 6 to 17, were in clinical remission at one year in Phase 3 SHINE-2 study

In key secondary outcomes, 71.2% of patients who responded to Omvoh induction achieved symptomatic remission and 50% achieved corticosteroid-free clinical remission at one year without surgery

INDIANAPOLIS, Oct. 19, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive late-breaking one-year results from the Phase 3 SHINE-2 study of Omvoh (mirikizumab-mrkz) in pediatric patients ages 6 to 17 with moderately to severely active ulcerative colitis (UC), including clinical, symptomatic and endoscopic outcomes. In the single-arm, open-label study, 81% of patients achieved clinical response to Omvoh induction at Week 12. Among responders, 50% achieved clinical remission at Week 52, meeting the study's primary endpoint.* Omvoh is the first IL-23p19 inhibitor to report one-year Phase 3 results in pediatric UC. These results were presented as a late-breaking oral presentation at United European Gastroenterology (UEG) Week 2026.¹

Omvoh is currently approved for adults with moderately to severely active UC. The safety and effectiveness of Omvoh in pediatric patients are currently being evaluated in clinical studies. Lilly plans to submit these data to global regulators to support a potential label expansion. If approved, Omvoh would be the first IL-23p19 inhibitor indicated for pediatric UC.

"For children and adolescents, the persistent bowel urgency, abdominal pain and unpredictability of ulcerative colitis can make a normal childhood feel out of reach, especially when symptoms return after previous treatments," said Mark Genovese, M.D., senior vice president of Lilly Immunology development. "Already approved for adults with ulcerative colitis, Omvoh is the first IL-23p19 inhibitor to report one-year Phase 3 results in pediatric ulcerative colitis. We look forward to working with regulators to potentially make Omvoh available to children and adolescents living with this disease, who continue to face substantial disease burden and ongoing unmet needs."

Unmet need in pediatric ulcerative colitis

UC affects more than 26,000 children and adolescents in the U.S.³ Although relatively uncommon, pediatric-onset UC is often more extensive and severe than disease that begins in adulthood.⁴ Up to half of children treated with corticosteroids become dependent on them, and up to one-third require surgery within a year.⁴

SHINE-2 evaluated Omvoh in a pediatric population with high disease burden and significant unmet need, including 54% of enrolled patients who had previously experienced biologic treatment failure. Half entered the study with severe disease activity as measured by the Pediatric Ulcerative Colitis Activity Index.¹

"For children with ulcerative colitis, every year spent relying on corticosteroids or facing the possibility of surgery can have important implications for growth, development and quality of life," said Marla C. Dubinsky, M.D., Professor of Pediatrics and Medicine at the Icahn School of Medicine at Mount Sinai, Chief of Pediatric Gastroenterology and Nutrition at Mount Sinai Kravis Children's Hospital. "Considering these challenges, the finding that half of the pediatric patients who responded to Omvoh achieved corticosteroid-free clinical remission without surgery at one year is particularly meaningful, especially in a population where many patients had previously experienced treatment failure with advanced therapies."

One-year results from SHINE-2 in children and adolescents with ulcerative colitis

Of the patients enrolled in SHINE-2, 81% achieved clinical response at Week 12. Among responders, ages 6 to 17, efficacy was sustained across multiple clinical, symptomatic and endoscopic outcomes at Week 52, including:

- 50% clinical remission (primary endpoint)*
- 50% corticosteroid-free clinical remission without surgery[†]
- 73.1% clinical response[‡]
- 71.2% symptomatic remission[¶]
- 53.8% endoscopic improvement[#]
- 44.2% endoscopic remission^{**}

The pediatric Week 52 clinical remission rate was similar to that observed among adult Week 12 responders treated with Omvoh in LUCENT-2 (50.7%).¹ This descriptive observation was separate from the primary endpoint analysis and should not be interpreted as a direct comparison between studies.

These one-year findings build on the early clinical, symptomatic and endoscopic improvements observed at Week 12, which were presented as a late-breaking oral presentation at the American College of Gastroenterology 2026 Annual Scientific Meeting.⁵

Safety findings from SHINE-2

Through Week 52 in SHINE-2, the safety profile of Omvoh in children and adolescents was consistent with its established safety profile in adults, with no new safety signals identified. The most common treatment-emergent adverse events in SHINE-2 were upper respiratory tract infection, injection site reaction, UC, headache, nasopharyngitis and anemia. Most treatment-emergent adverse events were mild to moderate in severity. Through Week 52, four patients (6.3%) experienced a serious adverse event; none was considered related to study treatment. Two patients (3.2%) discontinued treatment because of UC flare. No deaths, malignancies, opportunistic infections or growth-related safety concerns were reported through Week 52.¹

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 UC, Omvoh is also approved as a single-injection maintenance regimen in several countries around the world including the U.S., EU, Canada and Japan.

Lilly continues to study mirikizumab in pediatric inflammatory bowel disease, 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). Lilly is also evaluating mirikizumab through combination approaches and novel mechanisms aimed at delivering breakthrough induction efficacy while maintaining long-term remission and safety. These include studies in UC with eltekebart (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.

Disclosure: Dr. Dubinsky is a paid consultant for Lilly. She has not been compensated for any media work.

About SHINE-2

SHINE-2 is a Phase 3, multicenter, single-arm, open-label study evaluating mirikizumab in pediatric patients with moderately to severely active UC. A total of 63 participants, ages 4 to 17, were enrolled and received weight-based intravenous induction every four weeks for three doses (300 mg for patients >40 kg; 5 mg/kg for patients ≤40 kg). At Week 12, 52 patients entered the maintenance period as clinical responders and received weight-based subcutaneous mirikizumab every four weeks through Week 52. The primary endpoint was evaluated against a pre-specified benchmark derived from the adult placebo remission rate in the Phase 3 LUCENT-2 study.* The Week 52 efficacy results are reported for the Week 12 responder population (N=52; ages 6 to 17); safety results are based on all enrolled patients (N=63).

Patients completing SHINE-2 may be eligible to continue in SHINE-ON, an ongoing long-term extension study evaluating mirikizumab in pediatric patients with UC or Crohn's disease.

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.² The safety and effectiveness of Omvoh have not been established in pediatric patients.

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

Endnotes and References

*Clinical remission was defined as stool frequency (SF) subscore=0 or 1, rectal bleeding (RB) subscore=0 and endoscopic subscore (ES)=0 or 1 (excluding friability). The primary endpoint was met by exceeding a pre-specified benchmark based on the placebo remission rate in adults from the Phase 3 LUCENT-2 study. The lower bound of the 80% credible interval for the Week 52 pediatric remission rate among Week 12 responders (42.8%) exceeded the upper bound of the 90% credible interval for the adult placebo remission rate in LUCENT-2 (32.6%). Week 52 efficacy was assessed among the 52 patients who entered the maintenance period as Week 12 clinical responders, based on response status recorded by study sites.

†Corticosteroid-free clinical remission without surgery: clinical remission at Week 52 without surgery, and no corticosteroid use for at least 12 weeks prior to Week 52.

‡Clinical response: a decrease in the MMS of ≥2 points and ≥30% decrease from induction baseline plus a decrease of ≥1 point in the RB subscore from induction baseline or an RB subscore of 0 or 1.

¶Symptomatic remission: SF=0, or SF=1 with ≥1-point decrease from baseline and RB=0.

#Endoscopic improvement: ES=0 or 1, excluding friability.

**Endoscopic remission: ES=0.

¹Turner D, et al. Mirikizumab, the first IL-23p19 inhibitor to demonstrate sustained efficacy through 1 year in pediatric moderately-to-severely active ulcerative colitis: efficacy and safety findings from SHINE-2. United European Gastroenterology Week 2026; October 19, 2026; Barcelona, Spain.

²Omvoh. Prescribing Information. Lilly USA, LLC.

³Kappelman MD, Brensinger C, Parlett LE, Hurtado-Lorenzo A, Lewis JD. Prevalence of pediatric inflammatory bowel disease in the United States: pooled estimates from three administrative claims data sources. *Gastroenterology*. 2025;168(5):980-982.e2. doi:10.1053/j.gastro.2024.11.004

⁴Wine E, Aloï M, Van Biervliet S, et al. Management of paediatric ulcerative colitis, part 1: Ambulatory care— an updated evidence-based consensus guideline from the European Society of Paediatric Gastroenterology, Hepatology and Nutrition and the European Crohn's and Colitis Organisation. *J Pediatr Gastroenterol Nutr*. 2025;81(3):765-815. doi:0.1002/jpn3.70097

⁵Dubinsky M, et al. Mirikizumab induction therapy achieves early clinical, endoscopic, and biomarker improvement in children and adolescents with moderately to severely active ulcerative colitis: Week 12 results from the SHINE-2 study. American College of Gastroenterology 2026 Annual Scientific Meeting; October 14, 2026; Nashville, TN.

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.

MR HCP ISI CD APP

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.

Refer to: Kelly Hoffman; kelly.hoffman@lilly.com (Media)

Michael Czapar; czapar_michael_c@lilly.com (Investors)

The Lilly logo is rendered in a vibrant red, flowing script font. The letters are interconnected, with the 'L' and 'i' being particularly prominent and stylized. The overall shape is elongated and dynamic, capturing the essence of the company's branding.

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