Lilly's Omvoh (mirikizumab-mrkz) demonstrated early and sustained improvement in bowel urgency outcomes for patients with ulcerative colitis

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Phase 3b LUCENT-URGE is the first study in inflammatory bowel disease to assess bowel urgency across three measures — severity, frequency and stool deferral time — reflecting the spectrum of its burden on patients

By Week 12, patients experienced a 55% reduction in daily episodes of bowel urgency from baseline, with severity reduced by more than half by Week 28

At Week 28, nearly one-third of patients were able to delay using the restroom for at least 15 minutes after feeling urgency, up from 4% at baseline

INDIANAPOLIS, Oct. 27, 2025 /PRNewswire/ -- New data from Eli Lilly and Company (NYSE: LLY) showed Omvoh-treated patients with moderately to severely active ulcerative colitis (UC) and bowel urgency experienced early improvements in bowel urgency severity, frequency and stool deferral time by Week 12. These outcomes continued to improve through 28 weeks. The Phase 3b single-arm, open-label LUCENT-URGE study was specifically designed to assess bowel urgency and is the first in inflammatory bowel disease to include the novel endpoints of bowel urgency frequency and stool deferral time to more fully capture the patient experience. These results will be presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting, taking place Oct. 24-29 in Phoenix.[1]

"For many people with ulcerative colitis, the unpredictable and immediate need to find a restroom can be stressful and disrupt everyday activities, often forcing them to map restroom locations or to avoid important events," said David Rubin, M.D., Professor of Medicine and Director of the Inflammatory Bowel Disease Center at the University of Chicago Medicine. "These data build on prior Phase 3 and long-term results demonstrating Omvoh can reduce bowel urgency and help people regain control over a symptom that has often dictated their daily life."

In LUCENT-URGE, the following results were observed:[1]

- **Bowel urgency severity:** Bowel urgency severity was reduced by 52% at Week 28, with the average Urgency Numeric Rating Scale (UNRS) score dropping from 6.9 at baseline to 3.7 at Week 12 and 3.3 at Week 28.
- **Bowel urgency frequency:** Patients reported a 55% reduction from baseline in the number of times they experienced bowel urgency per day, from 6.9 times per day at baseline to 3.1 at Week 12, which was maintained at Week 28.
- **Stool deferral time:** The proportion of patients who were able to delay a bowel movement for at least 15 minutes or experienced no urgency in the previous 24 hours increased from 4.1% at baseline to 15.7% at Week 12 and 29.7% at Week 28, allowing them more time to reach a restroom.

Clinical, endoscopic and histologic improvements were consistent with previously disclosed LUCENT Phase 3 trial data. The 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. In LUCENT-URGE, 5.2% of patients reported a serious adverse event, while 4.7% discontinued treatment due to an adverse event.[1]

"Lilly is continuing to drive novel science in the study and treatment of bowel urgency because comprehensive control of ulcerative colitis must reflect the daily realities patients face, including the constant calculations and compromises they often make to navigate bowel urgency and its challenges," said Mark Genovese, M.D., senior vice president of Lilly Immunology development. "With Omvoh, we are delivering on our commitment to provide better patient outcomes."

The results from LUCENT-URGE build on the learnings from Lilly's CONFIDE study, which highlighted the often-overlooked burden of bowel urgency and other daily challenges faced by people living with UC. Lilly also recently disclosed four-year final data from LUCENT-3 in UC, including long-term outcomes in bowel urgency severity.

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 treating adults with UC or Crohn's disease and obesity with the concomitant use of mirikizumab with an incretin-based therapy. In addition, a trial of mirikizumab in pediatric patients is ongoing in UC (NCT05784246).

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 45 countries around the world.

About the LUCENT Clinical Trial Program
Omvoh was studied in two, Phase 3 clinical trials which evaluated the efficacy and safety of mirikizumab in adults with moderately to severely active ulcerative colitis (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) and LUCENT-2 (maintenance) studies included patients with inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, biologic therapy or JAKi.[2]

LUCENT-URGE, a Phase 3b, single arm, open-label study, evaluated the impact of Omvoh on bowel urgency in adults with moderately to severely

active UC and bowel urgency at baseline. Participants enrolled in LUCENT-URGE received Omvoh intravenously (300mg) at Weeks 0, 4 and 8, followed by subcutaneous dosing (200mg) every four weeks through Week 28. The study used baseline observation carried forward for continuous endpoints and non-responder imputation for binary endpoints. Participants were evaluated on bowel urgency severity, bowel urgency frequency, stool deferral time, clinical remission, endoscopic remission and histological-endoscopic mucosal improvement through Week 28, with the primary endpoint evaluating improvement in bowel urgency severity.[1]

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 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.[3]

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.

References
[1] Danese S, et al. Mirikizumab demonstrates rapid and sustained improvements in bowel urgency measures and clinical measures in patients with moderately-to-severely active ulcerative colitis: 28-week results from the Phase 3b LUCENT-URGE trial. 2025 American College of Gastroenterology Meeting. October 24–29, 2025.

[2] Sands, B, et al. Three-year efficacy and safety of mirikizumab following 152 weeks of continuous treatment for ulcerative colitis: results from the LUCENT-3 open-label extension study. Inflammatory Bowel Diseases, 2024;, izae253, https://doi.org/10.1093/ibd/izae253

[3] Omvoh. Prescribing Information. Lilly USA, LLC.

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