Lilly's Omvoh (mirikizumab-mrkz) is the first and only IL-23p19 antagonist to show four years of sustained, corticosteroid-free comprehensive patient outcomes in ulcerative colitis

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Approximately 80% of Omvoh-treated patients in the LUCENT-3 study who achieved clinical remission at one year maintained long-term, corticosteroid-free clinical and endoscopic remission

At four years, nearly all patients who achieved clinical remission at one year had improvements in bowel urgency, one of the most disruptive symptoms for patients

INDIANAPOLIS, Oct. 7, 2025 /PRNewswire/ -- New data from Eli Lilly and Company (NYSE: LLY) showed Omvoh (mirikizumab-mrkz) is the first and only interleukin-23p19 (IL-23p19) to help patients with moderately to severely active ulcerative colitis (UC) achieve sustained, long-term outcomes through four years. The results were seen across multiple symptomatic, clinical, endoscopic, histologic and quality-of-life measures, including among patients who had previously failed a biologic or advanced therapy (27%). These data are the final results from the LUCENT-3 Phase 3 open-label extension study and will be presented at United European Gastroenterology (UEG) Week, taking place Oct. 4-7 in Berlin.[1]

"Helping people with ulcerative colitis achieve long-term comprehensive disease control is a major goal for gastroenterologists, as it has remained out of reach for many patients," said Bruce Sands, M.D., M.S., Dr. Burrill B. Crohn Professor of Medicine and Chief of the Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai. "These long-term findings reinforce mirikizumab as a highly effective biologic for UC management, showing sustained clinical, endoscopic and steroid-free remission over four years, and improvement in bowel urgency, which can present a significant burden on patients' lives."

In LUCENT-3, the following results were observed after four years of total treatment among those who achieved clinical remission with Omvoh at one year in the Phase 3 LUCENT-2 study:

- 78% achieved corticosteroid-free clinical remission
- 78% sustained long-term clinical remission
- 81% sustained endoscopic remission, defined as an endoscopic subscore of 0 or 1 (excluding friability)
- 90% achieved remission on the Inflammatory Bowel Disease Questionnaire (IBDQ)
- 66% achieved histological-endoscopic mucosal improvement, an important marker of deep inflammation resolution
- 93% achieved a 3 or more-point reduction on the Urgency Numeric Rating Scale (UNRS)*, and 74% achieved UNRS = 0 or 1[1]

*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.

These data were also evaluated using a modified non-responder imputation (mNRI), presented in the About the LUCENT Clinical Trial Program section below.

These results build upon previously disclosed first-of-their-kind long-term results for Omvoh in both UC and Crohn's disease.

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.[1]

"With these results, Omvoh continues to set a high standard as the first and only IL-23p19 with evidence of sustained efficacy and consistent safety in ulcerative colitis over four years," said Mark Genovese, M.D., senior vice president of Lilly Immunology development. "Lilly is shaping the future of IBD care to make life better for patients by redefining what's possible in terms of steroid-free, long-lasting, comprehensive disease control, including durable clinical and endo-histologic remission and relief of disruptive symptoms like bowel urgency."

Beyond ongoing UC studies, including in pediatric patients (NCT05784246), Lilly is advancing 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 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 concomitant use of mirikizumab with an incretin-based therapy.

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 44 countries around the world.

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

About the LUCENT Clinical Trial Program
Omvoh was studied in two Phase 3 randomized, double-blind and placebo controlled clinical trials that evaluated the efficacy and safety of mirikizumab in adults with moderately to severely active ulcerative colitis (UC) and included patients who had never tried a biologic (biologic-naïve)

and harder-to-treat patients who had previously taken a biologic that failed. Patients (N=1279) were randomized 3:1 to receive Omvoh 300 mg IV or placebo IV Q4W at Weeks 0, 4, and 8 in the blinded induction study (LUCENT-1). Omvoh responders from LUCENT-1 (N=581) were re-randomized 2:1 to receive Omvoh 200 mg or placebo subcutaneous (SC) Q4W for 40 weeks in the blinded maintenance study (LUCENT-2) (52 weeks of continuous therapy). LUCENT-1 and LUCENT-2 studies included those who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, immunomodulators (6-mercaptopurine and azathioprine), biologic therapy (TNF blocker, vedolizumab) or Janus kinase inhibitors (JAKi, tofacitinib). Additionally, 41% of patients in LUCENT-1 had failed at least one biologic, 3% had failed a JAKi and 57% were biologic and JAKi-naïve.[2]

LUCENT-3, the single-arm long-term Phase 3 open-label extension of LUCENT-1 and LUCENT-2, evaluated the efficacy and safety of mirikizumab in patients with UC for an additional three years of treatment (up to four years total). Using a mNRI analysis to handle discontinuation and missing data, response rates among Week 52 mirikizumab remitters for major efficacy endpoints included: corticosteroid-free remission (62%), clinical remission (62%), endoscopic remission (66%), IBDQ remission (73%), histologic-endoscopic mucosal improvement (53%), 3 or more-point reduction on UNRS (75%) and UNRS = 0 or 1 (60%).[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-mkrz) 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]

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

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 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] 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.
[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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