Lilly's Omvoh (mirikizumab-mrkz) approved by U.S. FDA as a single-injection maintenance regimen in adults with ulcerative colitis

October 27, 2025

Omvoh now offers patients a simplified maintenance experience with one monthly injection, replacing the previous two-injection regimen

Omvoh single-injection dosing will be available for U.S. patients in early 2026

This is the third FDA approval for Omvoh this year, following approvals for Crohn's disease and a citrate-free formulation

INDIANAPOLIS, Oct. 27, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) approved a single-injection, once-monthly maintenance regimen (200 mg/2 mL) of Omvoh (mirikizumab-mrkz) for subcutaneous use in adults with moderately to severely active ulcerative colitis (UC).

"In clinical practice, we see that simplifying maintenance treatment can make a difference in the overall patient experience," said Miguel Regueiro, M.D., board-certified gastroenterologist specializing in inflammatory bowel disease. "A single monthly injection of Omvoh gives patients a regimen that's easier to manage alongside the unpredictability of living with ulcerative colitis."

The Omvoh single-injection, citrate-free maintenance dose will be available in the U.S. via prefilled pen or prefilled syringe in early 2026. The U.S. approval follows the recent European Union authorization of Omvoh for single-injection maintenance dosing for UC.

"People living with the constant discomfort and disruption caused by the symptoms of ulcerative colitis need treatments that offer the potential to achieve lasting remission and a convenient dosing option that fits easily into their lives," said George Salem, M.D., director of Crohn's and Colitis Center at OU HEALTH. "With this approval, patients who respond to induction therapy with Omvoh can continue maintenance therapy with the convenience of just one injection each month — delivering the same proven results with fewer injections."

The single-injection approval is based on results from a Phase 1 study comparing one 200 mg/2 mL subcutaneous injection to two 100 mg/1 mL injections in participants. The study confirmed that Omvoh single-injection is bioequivalent to the previously approved two-injection regimen.[1] Treatment with Omvoh for ulcerative colitis starts with 300-mg IV infusions every four weeks, for a total of three infusions, and at Week 12 transitions to subcutaneous self-injection every four weeks for maintenance treatment.

"At Lilly, we are committed to supporting people living with IBD by delivering meaningful clinical outcomes and continuing to improve their treatment experience," said Ashley Diaz-Granados, senior vice president of U.S. Immunology at Lilly. "Building on the introduction of a citrate-free formulation of Omvoh earlier this year, this approval further delivers on our commitment by providing patients the same outcomes in a single-injection maintenance regimen that fits more seamlessly into their lives."

Omvoh is approved in the U.S. 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. Through Lilly Support Services™, Lilly offers a patient support program including co-pay assistance for eligible, commercially insured patients.

INDICATIONS AND SAFETY SUMMARY

Omvoh® (ahm-VOH) is a medicine used to treat

- adults with moderately to severely active ulcerative colitis
- adults with moderately to severely active Crohn's disease

It is not known if Omvoh is safe and effective in children under 18 years of age.

Warnings – **Omvoh can cause serious side effects including:**

Serious allergic reactions: Omvoh may cause serious allergic reactions that may need to be treated in a hospital and may be life-threatening. Do not use Omvoh if you have had a serious allergic reaction to mirikizumab-mrkz or any of the ingredients in Omvoh. See the Medication Guide that comes with Omvoh for a list of ingredients. Stop using Omvoh and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

- fainting, dizziness, feeling lightheaded
- swelling of your face, eyelids, lips, mouth, tongue, throat, or trouble swallowing
- trouble breathing, throat tightening, or wheezing
- chest tightness
- fast heartbeat or pounding in your chest
- severe itching, hives, or redness all over your body
- sweating

Infections: Omvoh may lower the ability of your immune system to fight infections and may increase your risk of infections. If you have an infection, your healthcare provider should not start treatment with Omvoh until your infection is gone. Before starting treatment with Omvoh, your healthcare provider should assess you for tuberculosis (TB). If you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Omvoh. Your healthcare provider should watch you closely for signs and symptoms of TB while you are being treated with Omvoh and after treatment.

Before starting Omvoh, tell your healthcare provider if you think you have an infection or have symptoms of an infection, such as:

- fever, sweating, or chills
- muscle aches and pain
- cough or shortness of breath
- blood in your mucus (phlegm)
- flu-like symptoms
- headache
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- weight loss
- nausea or vomiting
- pain during urination

After starting Omvoh, tell your healthcare provider right away if you have any symptoms of an infection.

Liver Problems: Omvoh may cause liver problems. Your healthcare provider should do blood tests to check your liver enzyme and bilirubin levels before treatment, during, and after treatment with Omvoh. Your healthcare provider may hold or stop treatment if needed. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:

- unexplained rash
- nausea
- vomiting
- stomach-area (abdominal) pain
- feeling tired
- loss of appetite
- yellowing of the skin or the whites of your eyes
- dark urine

Common side effects

The most common side effects of Omvoh in people treated for ulcerative colitis include:

- upper respiratory infections
- injection site reactions
- joint pain
- rash
- headache
- herpes viral infections

The most common side effects of Omvoh in people treated for Crohn's disease include:

- upper respiratory infections
- injection site reactions
- headache
- joint pain
- elevated liver blood tests

These are not all the possible side effects of Omvoh.

Tell your doctor if you have any side effects. **You can report side effects at 1-800-FDA-1088 or *www.fda.gov/medwatch.***

Before you use Omvoh, review these questions with your doctor:

- Are you being treated for an infection?
- Do you have an infection that does not go away or keeps coming back?
- Do you have TB or have you been in close contact with someone with TB?
- Do you have any possible symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, or pain during urination?

Tell your doctor about all your medical conditions, including if:

- You have a history of serious allergic reaction to Omvoh, any infections or liver problems.
- You need any vaccines or have had one recently. Medicines that interact with the immune system may increase your risk of getting an infection after receiving live vaccines. You should avoid receiving live vaccines right before, during or right after treatment with Omvoh. Tell your healthcare provider that you are taking Omvoh before receiving a vaccine.
- You are pregnant, or plan to become pregnant. It is not known if Omvoh will harm your unborn baby. There will be a pregnancy registry to collect information about women who are exposed to Omvoh during pregnancy. If you become pregnant while taking Omvoh, you are encouraged to report your pregnancy to Eli Lilly and Company at 1-800-545-5979.
- You are breastfeeding or plan to breastfeed. It is not known if Omvoh passes into your breastmilk.
- You take prescription or over-the-counter medicines, vitamins, or herbal supplements.

How to take
Follow your healthcare provider's instructions for using Omvoh. You will receive your first 3 doses of Omvoh through a vein in your arm (intravenous infusion) in a healthcare facility by a healthcare provider every 4 weeks. Each infusion will last about 30 minutes (for ulcerative colitis) or about 90 minutes (for Crohn's disease). After induction, you will continue to receive Omvoh maintenance doses as self-injections under the skin (subcutaneous injection) every 4 weeks. For these injections, Omvoh is available as prefilled pens or prefilled syringes. (If taking Omvoh for Crohn's disease, you will need two injections to complete your dose, using either two prefilled pens or two prefilled syringes.) If you give injections at home, you should be trained on the correct way to prepare and inject Omvoh. Do not try to inject Omvoh yourself until you or your caregiver have been shown how to inject. **Read the detailed Instructions for Use about how to use and dispose of Omvoh the correct way.**

Learn more
Omvoh is a prescription medicine. During induction, Omvoh is available as a single-dose vial for intravenous infusion containing 300 mg/15 mL that is administered in a healthcare facility.

During maintenance, Omvoh is available as:

- For ulcerative colitis: one 200 mg/2 mL prefilled pen or prefilled syringe.
- For Crohn's disease: one 100 mg/mL prefilled pen or prefilled syringe and one 200 mg/2 mL prefilled pen or prefilled syringe.

For more information, call 1-800-545-5979 or go to **omvoh.lilly.com.**

This summary provides basic information about Omvoh but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Omvoh and how to take it. Your doctor is the best person to help you decide if Omvoh is right for you.

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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]

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

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.

References

[1] Otani Y, et al. One subcutaneous injection of mirikizumab is bioequivalent to two subcutaneous injections: results from a pharmacokinetic comparability study in healthy participants. 2025 United European Gastroenterology Week. October 4-7, 2025.

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

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