FDA approves Lilly's Omvoh® (mirikizumab-mrkz) for Crohn's disease, expanding its use to the second major type of inflammatory bowel disease

January 15, 2025

In the pivotal Phase 3 VIVID-1 trial, patients treated with Omvoh experienced significant improvement in clinical remission and endoscopic response at one year

Among those who achieved clinical remission and endoscopic response at one year, nearly 90% of patients maintained clinical remission with two years of continuous Omvoh treatment in open-label extension

INDIANAPOLIS, Jan. 15, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved Omvoh® (mirikizumab-mrkz) for the treatment of moderately to severely active Crohn's disease in adults. Omvoh is now approved in the U.S. for two types of inflammatory bowel disease (IBD), following its October 2023 approval as a first-in-class treatment for moderately to severely active ulcerative colitis (UC) in adults.[1]

Omvoh works to reduce inflammation within the gastrointestinal tract by targeting a specific protein, interleukin-23p19 (IL-23p19), which is a key contributor to intestinal inflammation. Omvoh is the first biologic treatment in more than 15 years to have disclosed two-year Phase 3 efficacy data in Crohn's disease at the time of approval.[2]

"The burden of Crohn's disease on patients' daily lives is substantial," said Michael Osso, president and chief executive officer, Crohn's & Colitis Foundation. "This approval is meaningful for adult patients with Crohn's disease, who now have more treatment options available."

This approval is based on positive results from the Phase 3 VIVID-1 study of Omvoh in adults with moderately to severely active Crohn's disease who had an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine and methotrexate) and/or biologics (TNF blockers, integrin receptor antagonists).[1] VIVID-1 was a randomized placebo-controlled trial of Omvoh. Patients randomized to placebo who did not achieve clinical response by patient-reported outcome at 12 weeks (40% of placebo patients) were subsequently switched to Omvoh treatment. Both primary endpoints in VIVID-1 were achieved:

- Clinical remission by Crohn's Disease Activity Index (CDAI) at one year
  - 53% of patients treated with Omvoh achieved clinical remission at one year versus 36% on placebo* ($p<0.001$).
- Endoscopic response at one year
  - 46% of patients treated with Omvoh had visible healing of the intestinal lining at one year versus 23% on placebo* ($p<0.001$).

Additionally, 32% of Omvoh patients achieved early improvement in endoscopic response, defined by visible healing of the intestinal lining, versus 11% on placebo at three months ($p<0.001$).

*Placebo included patients switched to treatment with Omvoh at 12 weeks.

Omvoh is also being studied in VIVID-2, an ongoing, open-label extension (OLE) study evaluating the efficacy and safety of Omvoh for up to three years in adults with moderately to severely active Crohn's disease. Among patients who achieved endoscopic response at one year in VIVID-1, over 80% maintained endoscopic response with one year of additional treatment (two years of continuous treatment). Additionally, among patients who achieved clinical remission and endoscopic response at one year in VIVID-1, nearly 90% of patients maintained clinical remission with one year of additional treatment (two years of continuous treatment).[3]

In both VIVID-1 and VIVID-2, Omvoh's overall safety profile in patients with moderately to severely active Crohn's disease was generally consistent with its known safety profile in patients with UC. The most common adverse reactions (reported in at least 5% of subjects and at a higher frequency than placebo during induction and through Week 52 of VIVID-1) associated with Omvoh treatment were upper respiratory tract infections, injection site reactions, headache, arthralgia and elevated liver tests. The labeling for Omvoh contains warnings and precautions related to hypersensitivity reactions, risk of infection, tuberculosis, hepatotoxicity and immunizations. See the Safety Summary below and full Prescribing Information.[1]

"Many patients with Crohn's disease have tried available therapies and are still seeking a treatment option that can work well for them to help control their disease," said Marla Dubinsky, M.D., chief, division of pediatric gastroenterology and nutrition, co-director, Susan and Leonard Feinstein IBD Clinical Center, Mount Sinai Kravis Children's Hospital, Icahn School of Medicine, Mount Sinai New York. "The FDA approval of Omvoh may help adults with Crohn's disease achieve long-term remission and visible healing of the intestinal lining, even if they have tried other medications that did not work or stopped working."

Lilly has also submitted marketing applications for Omvoh in Crohn's disease around the globe, including in the European Union and Japan. Additional global regulatory submissions are planned. In UC, Omvoh is currently approved in 44 countries.

"People living with Crohn's disease have shared with us how truly disruptive symptoms such as abdominal pain, frequent bowel movements and bowel urgency can be," said Daniel M. Skovronsky, M.D., Ph.D., chief scientific officer, and president of Lilly Research Laboratories and Lilly Immunology. "With Omvoh approved in both Crohn's disease and ulcerative colitis, more patients now have a treatment option that may provide long-term disease control and address key symptoms that matter most to them, reflecting Lilly's ongoing commitment to elevate care and improve outcomes for patients."

Lilly is committed to serving patients living with Crohn's disease and is working with insurers, health systems and providers to enable access to Omvoh. Effective Jan. 1, Omvoh has successfully gained first-line biologic coverage** from two of the three largest pharmacy benefit managers. Through Lilly Support Services™, Lilly offers a patient support program including co-pay assistance for eligible, commercially insured patients.

**First-line biologic coverage means Omvoh is available on formulary in the preferred specialty tier, alongside other products, and does not require failure of other biologic agents prior to use.

View the Omvoh brand logo.

About the VIVID Clinical Trial Program
VIVID-1 is a randomized, double-blind, placebo-controlled 52-week study. Patients received mirikizumab 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. Patients randomized to placebo who did not achieve clinical response by patient-reported outcome at 12 weeks (40% of placebo patients) were subsequently switched to Omvoh treatment. Clinical remission was defined as CDAI <150. Endoscopic response was defined as >50% reduction from baseline in Simple Endoscopic Score for Crohn's disease (SES-CD) total score, based on central reading. Bowel urgency was also assessed with an Urgency Numeric Rating Scale (UNRS) of 0 to 10.

Participants who completed Week 52 of VIVID-1 and, in the investigator's opinion, would derive clinical benefit from treatment with mirikizumab, were enrolled in VIVID-2. In VIVID-2, the primary objective is to evaluate the long-term effect of mirikizumab 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. Open-label extension studies may have selection bias as patients who cannot tolerate treatment or do not respond may drop out of the study prior to the extension.

About Omvoh®
Omvoh® (mirikizumab-mkrz) is an interleukin-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.

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

INDICATION 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. For a full dose you will need two injections with either two prefilled pens or two prefilled syringes. Inject 1 Omvoh prefilled pen or prefilled syringe followed right away by the other Omvoh prefilled pen or prefilled syringe. 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: two 100 mg/mL prefilled pens or prefilled syringes.
- 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 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 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.

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

[2] Data on File. Lilly USA, LLC. DOF-MR-US-0083.

[3] Data on File. Lilly USA, LLC. DOF-MR-US-0066.

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