Lilly's Omvoh® (mirikizumab) recommended by CHMP for approval in the European Union for adults with moderately to severely active Crohn's disease

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The Phase 3 VIVID-1 trial evaluated the safety and efficacy of Omvoh in patients with or without prior biologic failure and was the basis for the positive opinion

VIVID-1 was the first pivotal Crohn's disease trial to show benefits in hard-to-treat symptom of bowel urgency using a patient-centric scale

Omvoh will be the first treatment for Crohn's disease with results demonstrating improvements of histologic measures of inflammation included in its label, if approved by the European Commission

Lilly has also submitted Omvoh in the U.S. for approval to treat adults with moderately to severely active Crohn's disease, with a decision expected in the first half of 2025

INDIANAPOLIS, Dec. 13, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Omvoh® (mirikizumab), an interleukin-23p19 (IL-23p19) antagonist, for the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.

"I am excited for the potential of Omvoh as a novel treatment option for patients suffering from moderately to severely active Crohn's disease, since the majority of patients do not achieve remission on current therapies or cannot maintain it long term," said Stefan Schreiber, M.D., Ph.D., director of the Clinic for Internal Medicine I at Kiel Campus of the University Hospital Schleswig-Holstein, Kiel, Germany. "With Omvoh, many patients can achieve comprehensive control of their disease, including relief from disruptive symptoms such as bowel urgency and control of intestinal inflammation defined by visible endoscopic and histologic healing."

Omvoh was previously approved in the European Union, U.S. and Japan in 2023 as a first-in-class treatment for adults with moderately to severely active ulcerative colitis (UC) and is approved in 44 countries around the world. This positive opinion marks the next step toward European regulatory approval of Omvoh for patients with moderately to severely active Crohn's disease, and it is now referred to the European Commission for final action. The European Commission's decision is expected in the next one to two months.

The positive CHMP opinion is supported by data from the Phase 3 VIVID-1 study evaluating the safety and efficacy of mirikizumab compared with placebo and an active control (ustekinumab) in adults with moderately to severely active Crohn's disease. In VIVID-1, patients treated with mirikizumab achieved statistically significant improvement compared to placebo-treated patients on both co-primary endpoints, composite endoscopic response and composite clinical remission, and all major secondary endpoints, including composite steroid-free clinical remission and endoscopic outcomes, at Week 12 and Week 52. Additionally, improvements in bowel urgency severity were achieved, as measured by a patient-centric, 11-point scale developed by Lilly. VIVID-1 is the first pivotal Crohn's disease trial to report improvements in histologic outcomes with strict definitions that were aligned with the European Crohn's and Colitis (ECCO) position statement on mucosal histopathology. Histologic healing, as evaluated by these histologic measures of inflammation, is associated with better long-term outcomes for patients with Crohn's disease. Mirikizumab's overall safety profile in patients with moderately to severely active Crohn's disease was consistent with its known safety profile in patients with UC. Results from the VIVID-1 study were recently published in *The Lancet*.

In addition, long-term, multi-year, sustained efficacy and safety data for both UC and Crohn's disease were also recently presented at the American College of Gastroenterology (ACG) Annual Meeting in October.

"Disruptive symptoms of Crohn's disease, such as bowel urgency, can interfere with all aspects of life, leaving many people searching for treatments that can help them fully participate in the things that they enjoy," said Mark Genovese, M.D., senior vice president of Lilly Immunology development. "Given the efficacy we saw on clinical remission and endoscopic response, combined with the improvements in bowel urgency and histological inflammation, this positive CHMP opinion for Omvoh brings us a step closer to advancing care for more people with inflammatory bowel disease around the world."

Lilly has submitted marketing applications for Omvoh in Crohn's disease around the globe, including the U.S. and Japan. Decisions are expected from these regulatory authorities starting in the first half of 2025.

About Crohn's Disease
Crohn's disease is a chronic, inflammatory bowel disease associated with progressive bowel damage, disability and decreased health-related quality of life. If not adequately controlled, it may lead to complications that require hospitalization and surgical intervention. A substantial proportion of patients do not experience adequate treatment outcomes, have secondary loss of response to maintenance therapy or do not tolerate existing therapies, including biologic agents. Patients with previous biologic failure may be more difficult to treat.

About VIVID-1
VIVID-1 was a Phase 3, randomized, double-blind, treat-through study that evaluated the safety and efficacy of mirikizumab compared with placebo and an active control (ustekinumab) in adults with moderately to severely active Crohn's disease. Patients randomized to mirikizumab were administered 900 mg of mirikizumab intravenously at Week 0, 4 and 8, then 300 mg subcutaneously every four weeks from Weeks 12-52. In this study, 49% of patients taking mirikizumab or placebo had experienced a prior biologic failure.

Indications and Usage for Omvoh® (mirikizumab-mrkz) (in the United States)

Omvoh® is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

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 patient 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 (≥2%) associated with Omvoh treatment are upper respiratory tract infections and arthralgia during induction, and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance.

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 a one-time use prefilled pen or syringe with 100 mg/mL for subcutaneous injections. See Prescribing Information for dosing information.

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Please click for Prescribing Information and Medication Guide for Omvoh. Please click for Instructions for Use included with the device.

About Omvoh®

Omvoh® (mirikizumab) is an interleukin-23p19 antagonist indicated for the treatment of moderately to severely active ulcerative colitis 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 ulcerative colitis. Treatment of ulcerative colitis with Omvoh starts with 300-mg IV infusions, once every four weeks for a total of three infusions, and transitions to two, 100-mg subcutaneous injections every four weeks during maintenance treatment.

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 potential 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.

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