Lilly Completes Acquisition of Morphic to Improve Outcomes and Expand Options for People Living with Inflammatory Bowel Disease

August 16, 2024

Broadens Lilly's immunology pipeline with Morphic's oral integrin therapies, including MORF-057

Reinforces the company's strategy of delivering potential first or best-in-class therapies in the field of gastroenterology

INDIANAPOLIS, Aug. 16, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the successful completion of its acquisition of Morphic Holding, Inc. (NASDAQ: MORF). Morphic is a biopharmaceutical company developing oral integrin therapies for treatment of serious chronic diseases, including a selective oral small molecule inhibitor of α4β7 integrin (known as MORF-057) for inflammatory bowel disease (IBD).

"We are committed to exploring innovative approaches for immunologic diseases and believe Morphic's pipeline holds promise in improving outcomes and expanding treatment options for people with devastating conditions like IBD," said Daniel Skovronsky, M.D., Ph.D., chief scientific officer of Lilly and president, Lilly Research Laboratories and Lilly Immunology. "Acquiring Morphic reinforces our growing capabilities in gastroenterology, building on the strong foundation of Omvoh, our first-in-class molecule already approved and launched around the world for ulcerative colitis and under regulatory review for Crohn's disease. Further, the acquisition allows Lilly to research potential combination treatments that could better serve people beyond what is possible with currently available medicines."

The Offer and the Merger
Lilly's tender offer to acquire all of the issued and outstanding shares of common stock of Morphic (the "Shares"), at a purchase price of $57 per Share, net to the stockholder in cash, without interest thereon and subject to any applicable tax withholding, expired as scheduled at one minute past 11:59 p.m., Eastern time, on Aug. 15, 2024 and was not further extended. Computershare Trust Company, N.A., the depositary and paying agent for the tender offer, has advised Lilly that, as of the expiration of the tender offer, 46,731,511 Shares were validly tendered and not validly withdrawn, representing approximately 92.8% of the issued and outstanding Shares. Such Shares have been accepted for payment and will be promptly paid for in accordance with the terms of the tender offer. Following the completion of the tender offer, Lilly completed the acquisition of Morphic through the previously planned second-step merger. Morphic's common stock will be delisted from The Nasdaq Global Market.

For Lilly, Citi is acting as the exclusive financial advisor and Kirkland & Ellis LLP is acting as legal counsel. For Morphic, Centerview Partners LLC is acting as the exclusive financial advisor. Evercore Group L.L.C. also provided advice to Morphic. Fenwick & West LLP is acting as legal counsel for Morphic.

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 with Omvoh, 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.

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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-mrkz) 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.

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 more than 51 million 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. C-LLY

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements regarding Lilly's acquisition of Morphic, including the anticipated benefits and financial impact of the acquisition, Morphic's product candidates, including with respect to potential combination treatments involving Lilly's existing and future therapies, the delisting of Morphic's common stock, and ongoing and planned research and development. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements reflect current beliefs and expectations; however, these statements involve inherent risks and uncertainties, including with respect to drug research, development and commercialization, Lilly's evaluation of the accounting treatment of the acquisition and its potential impact on its financial results and financial guidance, risks that the acquisition disrupts current plans and operations or adversely affects employee retention and any legal proceedings that may be instituted related to the acquisition. Actual results could differ materially due to various factors, risks and uncertainties. Among other things, there can be no guarantee that Lilly will realize the expected benefits of the acquisition, that product candidates will be approved on anticipated timelines or at all, that any products, if approved, will be commercially successful, that Lilly's financial results will be consistent with its expected 2024 guidance or that Lilly can reliably predict the impact of the acquisition on its financial results or financial guidance. For further discussion of these and other risks and uncertainties, see Lilly's most recent 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 press release.

Refer to: Jordan Bishop; jordan.bishop@lilly.com; 317-374-1878 (Media)
Joe Fletcher; jfletcher@lilly.com; 317-296-2884 (Investors)

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