U.S. Food and Drug Administration Issues Complete Response Letter for Mirikizumab

April 13, 2023

INDIANAPOLIS, April 13, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced the U.S. Food and Drug Administration (FDA) has issued a complete response letter for the mirikizumab biologic license application (BLA) for the treatment of ulcerative colitis (UC). In the letter, the FDA cited issues related to the proposed manufacturing of mirikizumab, with no concerns about the clinical data package, safety, or label for the medicine.

"We remain confident in mirikizumab's pivotal Phase 3 clinical data and its potential to help people with ulcerative colitis," said Patrik Jonsson, Lilly executive vice president, president of Lilly Immunology and Lilly USA, and chief customer officer. "We are working diligently with the FDA and hope to launch mirikizumab in the U.S. as soon as possible."

Lilly recently received approval for mirikizumab as a first-in-class treatment for adults with moderately to severely active UC in Japan. In addition, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for mirikizumab as a first-in-class treatment for adults with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment. Regulatory decisions are anticipated in additional markets around the world in 2023.

About Lilly

Lilly unites caring with discovery to create medicines that 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 47 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/newsroom 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 mirikizumab, FDA approval, and Lilly's products, and reflects Lilly's current beliefs and expectations. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that future study results will be consistent with study findings to date, that future study results will be consistent with study results to date, that mirikizumab will receive certain regulatory approvals, or that it will be commercially successful. For further discussion of these and other risks and uncertainties, 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.

Refer to: Carla Cox; cox_carla@lilly.com; +1-317-750-3923 (Lilly media)
Joe Fletcher; jfletcher@lilly.com; +1-317-296-2884 (Lilly investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/us-food-and-drug-administration-issues-complete-response-letter-for-mirikizumab-301796847.html

SOURCE Eli Lilly and Company