U.S. Food and Drug Administration Issues Complete Response Letter for Lebrikizumab Based on Inspection Findings at Third-Party Manufacturer

October 2, 2023

In the letter, the FDA stated no concerns about the clinical data package, safety or label for lebrikizumab

INDIANAPOLIS, Oct. 2, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter for the lebrikizumab biologic license application (BLA) for the treatment of moderate-to-severe atopic dermatitis (eczema). The letter cited findings that arose during a multi-sponsor inspection of a third-party, contract manufacturing organization that included the monoclonal antibody drug substance for Lilly's lebrikizumab.

The letter stated no concerns about the clinical data package, safety or label for lebrikizumab. No other marketed or pipeline Lilly products are affected.

"We are confident in lebrikizumab's potential to help people living with eczema and in the clinical data that supports our submission package for the medicine," said Patrik Jonsson, Lilly executive vice president, president of Lilly Immunology and Lilly USA, and chief customer officer. "We will continue to work closely with the third-party manufacturer and the FDA to address the feedback in order to make lebrikizumab available to patients."

Lilly has submitted data to the FDA from ADvocate 1, ADvocate 2 and ADhere studies, which included over 1,000 adults and adolescents (ages 12 and older) with moderate-to-severe eczema who were unable to control their symptoms with topical medicines or other systemic treatments.

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 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/newsroom or follow us on Facebook, Instagram, Twitter 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 lebrikizumab, 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, or that lebrikizumab will receive certain regulatory approvals, or 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.

Refer to: Rachel Hoffmeyer; rachel.hoffmeyer@lilly.com; +1-463-276-8558 (Lilly media)
Joe Fletcher; jfletcher@lilly.com; +1-317-296-2884 (Lilly investors)

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