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Lilly Receives Positive CHMP Opinion for Ixekizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis

INDIANAPOLIS, Feb. 26, 2016 /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 ixekizumab for the treatment of moderate-to-severe plaque psoriasis in adults in the European Union (EU) who are candidates for systemic therapy. Ixekizumab is designed to specifically target IL-17A, a protein that plays a key role in driving underlying inflammation in psoriasis.¹

This is the first regulatory step toward approval for ixekizumab in Europe. The CHMP positive opinion is now referred for final action to the European Commission, which grants approval in the EU. The Commission usually makes a decision on marketing authorization within two to three months of the CHMP issuing its recommendation.

Psoriasis is a chronic autoimmune disease that affects the skin.² Psoriasis affects 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.^{2,3} Plaque psoriasis is the most common form of the condition and appears as raised, red patches of skin covered with a silvery, white buildup of dead skin cells, which are often painful or itchy.² The exact cause of psoriasis is unknown, though genetics and environmental factors are known to play a role in the development of the disease.² In addition to physical symptoms, psoriasis can have a significant impact on an individual's quality of life and has been associated with an increased risk of other serious health conditions, including diabetes and heart disease.²

"Psoriasis is a serious, chronic disease that can also have a significant, and sometimes debilitating, psychological and social impact," said Andrew Hotchkiss, president of Lilly's European and Canadian operations. "This CHMP positive opinion is a significant milestone in our quest to offer physicians a new treatment option for their patients with moderate-to-severe plaque psoriasis."

The CHMP positive opinion for ixekizumab was based on findings from the largest Phase 3 trial program in moderate-to-severe plaque psoriasis evaluated by regulatory authorities to date. This clinical program included three double-blind, multicenter, Phase 3 studies—UNCOVER-1, UNCOVER-2 and UNCOVER-3—which demonstrated the safety and efficacy of ixekizumab in more than 3,800 patients in 21 countries with moderate-to-severe plaque psoriasis. All three studies evaluated the safety and efficacy of ixekizumab (80 mg every two weeks, following a 160-mg starting dose) compared to placebo after 12 weeks. UNCOVER-2 and UNCOVER-3 included an additional comparator arm in which patients received etanercept (50 mg twice a week) for 12 weeks.

In these studies, the co-primary efficacy endpoints at 12 weeks were Psoriasis Area Severity Index (PASI) 75 and static Physician's Global Assessment (sPGA) 0 or 1.¹ PASI measures the extent and severity of psoriasis by assessing average redness, thickness and scaliness of skin lesions (each graded on a zero to four scale), weighted by the body surface area of involved skin, while the sPGA is the physician's assessment of severity of a patient's psoriasis lesions overall at a specific point in time and is a required measure the FDA uses to evaluate effectiveness.⁴

About Ixekizumab

Ixekizumab is an IgG4 monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine (< 3pM) and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of pro-inflammatory cytokines and chemokines.

About the UNCOVER Studies

The UNCOVER-1, UNCOVER-2 and UNCOVER-3 studies are double-blind, multicenter, Phase 3 studies evaluating more than 3,800 patients with moderate-to-severe psoriasis in 21 countries. All three studies evaluated the safety and efficacy of different dosing regimens of ixekizumab (80 mg every two or four weeks, following a 160-mg starting dose) compared to placebo after 12 weeks. UNCOVER-2 and UNCOVER-3 included an additional comparator arm in which patients received etanercept (50 mg twice a week) for 12 weeks. In UNCOVER-1, UNCOVER-2 and UNCOVER-3, safety and efficacy was further evaluated through 60 weeks.

About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.² It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells.² Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.^{2,3} Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease.² The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.²

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels.

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about ixekizumab as a potential treatment for moderate-to-severe plaque psoriasis, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that ixekizumab will receive additional regulatory approvals to be commercially successful. 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 release.

¹ Krueger JG, Fretzin S, Suárez-Fariñas M, et al. IL-17A is essential for cell activation and inflammatory gene circuits in subjects with psoriasis. *J Allergy Clin Immunol.* 2012;130(1):145-54.

² Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed February 25, 2016.

³ Psoriasis. American Academy of Dermatology website. <https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis>. Accessed February 25, 2016.

⁴ Feldman SR, Krueger GG. Psoriasis assessment tools in clinical trials. *Ann Rheum Dis.* 2005;64:ii65-ii68. http://ard.bmj.com/content/64/suppl_2/ii65.full. Accessed February 25, 2016.

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Refer to: Jen Dial; dial_jennifer_kay@lilly.com; +1-317-220-1172



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