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Ixekizumab Demonstrates Rapid, Clinically Meaningful Improvements as Early as One Week among Patients with Moderate-to-Severe Plaque Psoriasis

- In a combined analysis of UNCOVER-2 and UNCOVER-3, significant improvement of psoriasis plaques was observed in patients treated with ixekizumab at one, two and four weeks -

INDIANAPOLIS, March 4, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that treatment for moderate-to-severe plaque psoriasis with ixekizumab resulted in clinically meaningful improvements as early as one week, compared to patients treated with etanercept or placebo. Detailed results of this combined analysis of UNCOVER-2 and UNCOVER-3 were presented during the American Academy of Dermatology (AAD) Annual Meeting taking place March 4-8 in Washington, D.C.

UNCOVER-2 and UNCOVER-3 are double-blind, multicenter, Phase 3 studies evaluating more than 2,500 patients with moderate-to-severe plaque psoriasis across 19 countries. In these comparator studies, patients were assigned to receive either placebo, etanercept (50 mg twice a week) or ixekizumab (80 mg every two or four weeks) for 12 weeks, following a 160-mg starting dose.

This combined analysis evaluated the speed of onset of clinical improvement as measured by mean percentage improvement in Psoriasis Area Severity Index (PASI) score from baseline, as well as time to PASI 50 and PASI 75 among patients treated with ixekizumab, etanercept or placebo. 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.^[1]

"Studies have shown that clinical improvement observed early during psoriasis treatment can help predict clinical response at later times,^[2]" said Craig Leonardi, M.D., lead study author and clinical professor of dermatology at St. Louis University School of Medicine. "In this analysis of ixekizumab, early results were seen in patients with moderate-to-severe plaque psoriasis, an extensive and difficult-to-treat disease. According to patients and their dermatologists, rapid clearing of psoriasis plaques is one of the most important attributes for treatment success."

Significant differences in mean percentage improvement of psoriasis plaques were observed among patients treated with ixekizumab compared to etanercept and placebo:

- ▮ At one week, the mean percentage improvement was 32.7 percent in the group randomized to receive ixekizumab every two weeks, 10.3 percent in etanercept and 5.31 percent in placebo ($p < 0.001$ for all comparisons).
- ▮ At two weeks, the mean percentage improvement was 53.6 percent in the group randomized to receive ixekizumab every two weeks, 23.3 percent in etanercept and 9.25 percent in placebo ($p < 0.001$ for all comparisons).

Treatment with ixekizumab also resulted in clinically meaningful improvements (PASI 50) as early as one week, which were statistically significantly different compared with etanercept and placebo.

- ▮ At one week, PASI 50 was achieved by 22.8 percent of patients treated with ixekizumab every two weeks compared to 3.9 percent among those treated with etanercept and 1.4 percent in placebo ($p < 0.001$ for all comparisons).
- ▮ At two weeks, PASI 50 was achieved among 58.8 percent of patients treated with ixekizumab every two weeks compared to 14.6 percent of those treated with etanercept and 4.2 percent in placebo ($p < 0.001$ for all comparisons).

Median time to PASI 75 was 30 days among patients treated with ixekizumab every two weeks and 85 days among those treated with etanercept.

The majority of treatment-emergent adverse events were mild or moderate. The most frequently reported adverse drug reactions were injection site reactions and upper respiratory tract infections (most frequently nasopharyngitis) and generally did not lead to treatment discontinuations. Overall, the safety profile was comparable to etanercept in these two clinical studies.

Ixekizumab is the company's investigational medicine for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis.

About Ixekizumab

Ixekizumab is an IgG4 monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine 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 Moderate-to-Severe Plaque Psoriasis

[Psoriasis](#) is a chronic, immune disease that affects the skin.^[3] It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells.^[3] Psoriasis affects approximately 7.5 million Americans and 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.^{[3],[4]} Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease.^[3] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.^[3]

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 or 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] 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 29, 2016.

[2] Seston EM, Ashcroft DM, Griffiths CE. Balancing the benefits and risks of drug treatment: a stated-preference, discrete choice experiment with patients with psoriasis. *Arch Dermatol*. 2007;143:1175-1179.

[3] Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed March 3, 2016.

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

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