



March 7, 2016

## **Studies Show Ixekizumab Improved Work Productivity for Patients with Moderate-to-Severe Plaque Psoriasis: Results Published in JAMA Dermatology**

**- Results from the UNCOVER-1 study will also be presented at the American Academy of Dermatology (AAD) Annual Meeting, March 4-8, 2016, in Washington, D.C. -**

INDIANAPOLIS, March 7, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that *JAMA Dermatology* has published detailed results from three pivotal Phase 3 trials that evaluated the effect of ixekizumab on work productivity in patients with moderate-to-severe plaque psoriasis. Specific results from the UNCOVER-1 study were also presented Monday during the American Academy of Dermatology (AAD) Annual Meeting in Washington, D.C.

In an analysis of the UNCOVER-1, UNCOVER-2 and UNCOVER-3 studies, the effect of ixekizumab on work productivity was evaluated by the change from baseline as measured by Work Productivity and Activity Impairment-Psoriasis (WPAI-PSO) scores at 12 weeks. The validated, self-reported WPAI questionnaire is used to measure impairment of work activities due to general health or a specific condition.<sup>1</sup>

In all three studies, patients treated with ixekizumab reported improved work productivity compared to patients treated with placebo. In UNCOVER-1, improvements in work productivity were also sustained up to 60 weeks in those who demonstrated initial clinical response to ixekizumab at 12 weeks.

"Psoriasis is a serious, systemic disease that can have a significant impact on a patient's overall health and quality of life, including work productivity and overall activity levels," said April Armstrong, M.D., MPH, corresponding study author and associate dean of clinical research at Keck School of Medicine of University of Southern California. "The results presented at AAD and detailed in *JAMA Dermatology* further reinforce published data supporting ixekizumab as a potential treatment for moderate-to-severe plaque psoriasis. If approved, ixekizumab may provide dermatologists with a new option to address both skin symptoms and health-related outcomes for patients, including work-related activities."

In all three studies, patients treated with ixekizumab every two weeks demonstrated the following results at 12 weeks:

- ┆ In UNCOVER-1, patients treated with ixekizumab showed significantly greater improvement compared to placebo in all WPAI-PSO scores: absenteeism, presenteeism, work productivity loss and activity impairment ( $p < 0.001$  for all comparison scores).
- ┆ In UNCOVER-2, patients treated with ixekizumab showed significantly greater improvement compared to placebo in all WPAI-PSO scores: absenteeism ( $p=0.016$ ), presenteeism ( $p < 0.001$ ), work productivity loss ( $p < 0.001$ ) and activity impairment ( $p < 0.001$ ). Patients treated with ixekizumab also showed significantly greater improvement in the following WPAI scores compared to those treated with etanercept: presenteeism, work productivity loss and activity impairment ( $p < 0.001$  for all comparison scores).
- ┆ In UNCOVER-3, patients treated with ixekizumab showed statistically significant improvements compared to placebo in all WPAI-PSO scores: absenteeism ( $p=0.012$ ), presenteeism ( $p < 0.001$ ), work productivity loss ( $p < 0.001$ ) and activity impairment ( $p < 0.001$ ). Patients treated with ixekizumab also showed significantly greater improvement in activity impairment scores compared to those treated with etanercept ( $p=0.009$ ).

Improvements in WPAI scores were also sustained through 60 weeks among patients who achieved clinical response with ixekizumab at 12 weeks. In UNCOVER-1 and UNCOVER-2, significant improvements from baseline were sustained through 60 weeks among patients treated with ixekizumab for presenteeism, work productivity loss and activity impairment scores.

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.

In these studies, patients were randomized to receive different dosing regimens of ixekizumab (80 mg every two weeks or four weeks, following a 160-mg starting dose), or placebo, for 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.

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 appears on the skin.<sup>2</sup> It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells.<sup>2</sup> Psoriasis affects approximately 7.5 million Americans and 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.<sup>2,3</sup> Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease.<sup>2</sup> The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.<sup>2</sup>

## 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](http://www.lilly.com) and [newsroom.lilly.com/social-channels](http://newsroom.lilly.com/social-channels).

## P-LLY

*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] Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *PharmacoEconomics*. 1993;4(5):353-365.

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

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

**Refer to:** Jen Dial; [dial\\_jennifer\\_kay@lilly.com](mailto:dial_jennifer_kay@lilly.com); 317-220-1172 (Lilly BioMedicines)



Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/studies-show-ixekizumab-improved-work-productivity-for-patients-with-moderate-to-severe-plaque-psoriasis-results-published-in-jama-dermatology-300231804.html>

SOURCE Eli Lilly and Company

News Provided by Acquire Media