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New Head-to-Head Data Shows Significantly Higher Response Rates for Lilly's Taltz® (ixekizumab) Compared to Stelara® (ustekinumab) in Patients with Moderate-to-Severe Plaque Psoriasis

Lilly to present head-to-head 24-week data comparing the efficacy and safety of Taltz and Stelara for the treatment of moderate-to-severe plaque psoriasis

INDIANAPOLIS, March 4, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) announced today that patients with moderate-to-severe plaque psoriasis treated with Taltz® (ixekizumab) demonstrated superior efficacy at 24 weeks compared to patients treated with Stelara®* (ustekinumab). Detailed results from the IXORA-S study were presented during the American Academy of Dermatology (AAD) Annual Meeting taking place March 3-7 in Orlando, Fla.

At 24 weeks, patients treated with Taltz achieved significantly higher response rates compared to patients treated with Stelara, including 83 percent of patients who achieved Psoriasis Area Severity Index (PASI) 90—the study's primary endpoint—compared to 59 percent of patients who achieved PASI 90 after treatment with Stelara.

"For many years, achieving PASI 75 - or 75 percent improvement in skin plaques - has been the standard treatment goal for moderate-to-severe plaque psoriasis," said Kristian Reich, M.D., Ph.D., lead author and professor, Georg-August-University Göttingen and Dermatologikum Hamburg, Hamburg, Germany. "With the introduction of treatments like Taltz, dermatologists can offer treatment options that allow more patients to achieve PASI 90 or PASI 100. The data of the IXORA-S study is significant, as it demonstrates both high levels of skin improvement for patients treated with Taltz, consistent with pivotal Phase 3 trials, as well as higher response rates over Stelara, which is one of the most frequently used biologics in the treatment of moderate-to-severe plaque psoriasis."

In the IXORA-S study, patients were randomized to receive either Stelara (45 mg or 90 mg weight-based dosing per label) or Taltz (80 mg every two weeks for 12 weeks followed by 80 mg every four weeks), following a 160-mg starting dose, for a total of 52 weeks.

This study also evaluated PASI 75, PASI 100 and static Physician's Global Assessment score (sPGA) 0 or 1 with at least a two-point improvement from baseline. 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] 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.[1]

At 24 weeks, patients treated with Taltz achieved significantly higher response rates compared to patients treated with Stelara, as demonstrated by the following:

- 91.2 percent of patients treated with Taltz achieved PASI 75 compared to 81.9 percent of patients treated with Stelara ($p=0.015$);
- 83.1 percent of patients treated with Taltz achieved PASI 90 compared to 59.0 percent of patients treated with Stelara ($p < 0.001$);
- 49.3 percent of patients treated with Taltz achieved PASI 100 compared to 23.5 percent of patients treated with Stelara ($p=0.001$).

Additionally, 86.6 percent of patients treated with Taltz achieved sPGA 0 or 1 compared to 69.3 percent of patients treated with Stelara after 24 weeks ($p < 0.001$).

The majority of treatment-emergent adverse events were mild or moderate. There were no statistically significant differences between treatment groups in overall treatment-emergent adverse events. The safety profile for Taltz was consistent with previous clinical trials.

"The approval of Taltz in the U.S., Canada and Europe nearly one year ago introduced a treatment option that could help patients with moderate-to-severe plaque psoriasis achieve virtually clear or completely clear skin," said Dr. Lotus Mallbris,

global brand development leader, Taltz, Eli Lilly and Company. "We are thrilled with the opportunity to share this new data with dermatologists at AAD, as it reinforces the clinical benefits of Taltz for patients with moderate-to-severe plaque psoriasis."

Results from Phase 3 trials evaluating Taltz for the treatment of active psoriatic arthritis are expected to be presented later this year. Taltz is also in Phase 3 trials for the treatment of axial spondyloarthritis.

Indications and Usage

Taltz® (ixekizumab) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

Taltz may increase the risk of infection. The Taltz group had a higher rate of infections than the placebo group (27% vs. 23%). Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Patients receiving Taltz should be monitored closely for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including anaphylaxis, angioedema and urticaria, have been reported with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease

Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease.

Immunizations

Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Live vaccines should not be given with Taltz.

ADVERSE REACTIONS

Most common adverse reactions (> 1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections.

Please see accompanying Prescribing Information and Medication Guide. Please see Instructions for Use included with the device.

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About Taltz® (ixekizumab)

Taltz® (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. Taltz 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.[2] It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. 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 Taltz (ixekizumab) as a 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 Taltz 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 March 1, 2017.
[2] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed March 1, 2017.
[3]Psoriasis. American Academy of Dermatology website. https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis. Accessed March 1, 2017.

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