



Lilly to Present 5-Year Sustained Efficacy and Safety Results for Taltz® (ixekizumab) in Patients with Plaque Psoriasis at the World Congress of Dermatology

June 11, 2019

INDIANAPOLIS, June 11, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the company will present positive, five-year Phase 3 data for Taltz® (ixekizumab). Patients with moderate- to severe plaque psoriasis who continued to receive Taltz maintained high levels of skin clearance with no unexpected safety outcomes for up to five years of treatment. These data will be presented at the World Congress of Dermatology (WCD) in Milan, Italy on June 11.

"Of patients who continued to take Taltz through five years in the extension period of this study, more than 90 percent maintained significant skin clearance as measured by PASI 75 and almost half of patients maintained completely clear skin," said Craig Leonardi, M.D., lead investigator of the study and adjunct professor of dermatology at St. Louis University School of Medicine. "These results demonstrate that patients taking Taltz can achieve sustained skin clearance over the five-year treatment period."

Patients who were static Physician's Global Assessment (sPGA) 0/1 responders at Week 12 and who completed 60 weeks of treatment could enter the open-label extension period of UNCOVER-1 (n=110). In the extension period of the study, Taltz demonstrated sustained response from Week 60 through Week 264 in patients who continuously received on-label dosing (160 mg starting dose, 80 mg every two weeks [Q2W] through Week 12, and every four weeks [Q4W] thereafter). Response rates were maintained over the five-year period, with Psoriasis Area and Severity Index (PASI) 75, 90 and 100 response rates of 94.3 percent, 81.8 percent and 46.6 percent, respectively at week 264.

"Lilly is committed to helping people living with immune-mediated diseases, including moderate- to severe plaque psoriasis," said Rhonda Pacheco, Pharm.D., global brand development leader for immunology at Lilly. "These results reaffirm that the high levels of skin clearance Taltz can provide early in treatment may be sustained over a long period of time."

During Weeks 60-264, treatment-emergent adverse events were consistent with previous studies of Taltz from the UNCOVER program. Additionally, there were no new or unexpected safety findings during the extension period. Four-year data from UNCOVER-3 will also be presented at the WCD.

The Taltz safety profile has been studied in 13 clinical trials in moderate- to severe plaque psoriasis with a total exposure of more than 17,000 patient-years as part of the Taltz clinical trial program.

Later this year, Lilly plans to announce the results from IXORA-R, a clinical trial designed to evaluate superiority between Taltz and Tremfya® (guselkumab) in adult patients with moderate- to severe plaque psoriasis.

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of adults with active psoriatic arthritis. Taltz is also approved to treat adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION FOR TALTZ

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. In clinical trials of patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of patients with psoriatic arthritis. 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. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including angioedema and urticaria (each ≤0.1%), occurred in the Taltz group in clinical trials. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use 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 in patients with plaque psoriasis. 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. Avoid use

of live vaccines in patients treated 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. Overall, the safety profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please see accompanying [Prescribing Information](#) and [Medication Guide](#). Please see [Instructions for Use](#) included with the device.

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About Taltz®

Taltz® (ixekizumab) is a 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.¹ 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.^{1,2} Psoriasis can occur on any part of the body, including the genital area.¹ Up to 63 percent of psoriasis patients experience genital psoriasis over the course of their 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.¹ Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease.¹

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 www.lilly.com/newsroom/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 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 future study results will be consistent with the results to date or 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 Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed May 2, 2019.

² Skin conditions by the numbers. American Academy of Dermatology website. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed May 2, 2019.

³ Ryan C, et al. J Am Acad Dermatol. 2015;72:978-983

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