



Lilly Announces Initiation of IXORA-R Head-to-Head Trial Comparing Taltz® and Tremfya® in Patients with Moderate-to-Severe Plaque Psoriasis

September 10, 2018

INDIANAPOLIS, Sept. 10, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the initiation of the IXORA-R head-to-head (H2H) clinical trial, designed to evaluate superiority between Taltz® (ixekizumab) and Tremfya® (guselkumab) in adult patients with moderate-to-severe plaque psoriasis. The IXORA-R study will be the first H2H trial between an IL-17 and IL-23 using the Psoriasis Area Severity Index (PASI) 100 score as the primary endpoint.

"Lilly is committed to minimizing the burden for people with immune-mediated inflammatory diseases, including moderate-to-severe plaque psoriasis," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "Head-to-head trials can provide robust evidence that helps advance clinical practice. We hope the results of this new study will provide valuable insights to patients and their providers."

The IXORA-R study, which is set to be completed by the end of 2019, aims to enroll 960 patients and is a 24-week multicenter, randomized, blinded, parallel-group study comparing the efficacy and safety of Taltz to Tremfya in patients with moderate-to-severe plaque psoriasis. The primary endpoint of the study is the proportion of patients who achieve 100% improvement from their baseline as measured by PASI 100 at week 12. Secondary endpoints include: the proportion of patients achieving PASI 75 as early as week 2 and PASI 100 at weeks 4, 8 and 24; and the proportion of patients achieving a Static Physician Global Assessment (sPGA) score of 0 at week 12.

"The primary endpoint of this study is PASI 100, which emphasizes that the goal of treatment should be complete skin clearance," said Alice Gottlieb, M.D., Ph.D., Professor of Dermatology at New York Medical College. "This study could help raise awareness of treatment goals for moderate-to-severe plaque psoriasis that patients can explore with their doctors."

IXORA-R is part of the expansive clinical development program for Taltz in psoriatic disease. In addition to IXORA-R, SPIRIT-H2H is a head-to-head clinical trial comparing Taltz to Humira® (adalimumab) in adult patients with psoriatic arthritis, which is scheduled to be completed in early 2019.

The Taltz safety profile has been studied in 12 clinical trials in moderate-to-severe plaque psoriasis with a total exposure of more than 15,000 patient-years and four clinical trials in psoriatic arthritis with more than 1,300 patient-years as part of the Taltz clinical trial program.^{1,2,3}

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 $\leq 0.1\%$), 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.⁴ 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.^{4,5} Psoriasis can occur on any part of the body, including the genital area.⁴ Up to 63 percent of psoriasis patients experience genital psoriasis over the course of their disease.⁶ The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.⁴ Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease.⁴

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) in patients with moderate-to-severe plaque psoriasis and psoriatic arthritis, 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, 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 Data on File [t_tea1ptex_safety_aps]. Eli Lilly and Company 2017.

² Data on File [t_teasocecx_safety_aps]. Eli Lilly and Company 2016.

³Philippe Goupille, Euthalia Roussou, Gerd-Rüdiger Burmester, Philip Mease, Alice Gottlieb, Sandra Garces, Olivier Benichou, David H. Adams, Wen Xu, Peter Nash. Safety of Ixekizumab in Patients with Psoriatic Arthritis: Results from a Pooled Analysis of Three Clinical Trials. *Ann Rheum Dis*. 2018;77(Suppl 2):1039-1040.

⁴ Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed September 10, 2018.

⁵ Skin conditions by the numbers. American Academy of Dermatology website. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed September 10, 2018.

⁶ Ryan C, et al. *J Am Acad Dermatol*. 2015;72:978-9831

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