



Lilly Announces Positive Top-Line Results for Second Phase 3 Study of Taltz® (ixekizumab) in Ankylosing Spondylitis (Radiographic Axial Spondyloarthritis) for TNF Inhibitor-Experienced Patients

June 28, 2018

INDIANAPOLIS, June 28, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that Taltz® (ixekizumab) met the primary and major secondary endpoints in COAST-W, a Phase 3 study evaluating the safety and efficacy of Taltz for the treatment of Ankylosing Spondylitis (AS), also known as radiographic axial spondyloarthritis (r-axSpA). This is the first AS study focusing on a difficult-to-treat population of patients who had an inadequate response to one or two tumor necrosis factor (TNF) inhibitors (90 percent of enrolled patients) or intolerance to a TNF inhibitor (10 percent).

Taltz demonstrated a statistically significant improvement in the signs and symptoms of AS, as measured by the proportion of patients who achieved Assessment of Spondyloarthritis International Society 40 (ASAS40) response at 16 weeks, when compared to placebo. COAST-W is part of the clinical development program for Taltz in AS, the first to use ASAS40 across the program as the primary endpoint to define treatment success, rather than the traditionally used endpoint of ASAS20.

AS is one type of spondyloarthritis that affects the pelvic joints and spine, and can be characterized by chronic inflammatory back pain, stiffness and impaired function and mobility.¹ Of those affected by AS, approximately 80 percent will experience symptoms before age 30.²

"These positive results, in combination with previous results from the Phase 3 COAST-V study, provide further support for Taltz as a potential treatment option for patients with AS, including those who have had an inadequate response to treatment with TNF inhibitors, a difficult-to-treat population," said Dr. Lotus Mallbris, vice president, Immunology Development. "By using ASAS40 as the primary endpoint in our clinical development program, we hope to establish a higher treatment target goal for AS patients. We look forward to sharing additional clinically meaningful data from this study, and remain committed to continuing our research to evaluate potential treatment options that deliver better outcomes for patients living with this disease."

In COAST-W, the incidence of serious adverse events was similar with Taltz compared with placebo. The most common adverse events observed were consistent with other Phase 3 studies of ixekizumab.

Lilly plans to submit detailed data from COAST-W for disclosure at scientific meetings and in peer-reviewed journals later this year. Based on the positive results from the COAST-V and COAST-W studies, the company plans to submit for U.S. regulatory approval in AS later this year.

Indications and Usage

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

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

During Taltz treatment, monitor patients for onset or exacerbations of 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.

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 ($\geq 1\%$) 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 click to access the [Prescribing Information](#) and [Medication Guide](#). Please click to access [Instructions for Use](#) included with the device.

About the COAST-W Study

COAST-W is a multicenter, randomized, double-blind, placebo-controlled 16-week study followed by long-term evaluation of efficacy and safety of ixekizumab in patients who had an inadequate response or were intolerant to one or two tumor necrosis factor (TNF) inhibitors. In the study, patients were treated with 80 mg of Taltz SC either every two weeks or every four weeks (following a 80 mg or 160 mg starting dose at Week 0), or placebo. Patients were required to have an established diagnosis of AS with active disease defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Numeric Rating Scale (NRS) score ≥ 4 and a total back pain NRS score ≥ 4 and an inadequate response or intolerance to one or two TNF inhibitors. The primary efficacy endpoint was the proportion of patients at 16 weeks who achieved ASAS40 response, which represents a 40 percent improvement in disease signs and symptoms such as pain, inflammation and function.

About the Taltz Program in axSpA

The COAST-W study is part of a clinical development program that aims to evaluate the efficacy and safety of ixekizumab across various population subsets of patients with axSpA. The COAST program includes three registration studies, each of one year duration: COAST-V in patients with AS/active radiographic axSpA who are bDMARD-naïve; COAST-W in patients with AS/active radiographic axSpA who previously had an inadequate response or intolerance to TNF inhibitors; and COAST-X in patients with non-radiographic axSpA who are bDMARD-naïve. Patients may enroll into a long-term extension study after completion of any of the registration studies to receive ixekizumab treatment for up to an additional two years.

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 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 potential treatment for Ankylosing Spondylitis, 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 Spondyloarthritis. American College of Rheumatology website. <http://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Spondyloarthritis>. Accessed May 4, 2018.

² Sieper, J., Braun, J. Overview of axial spondyloarthritis. Clinician's Manual on Axial Spondyloarthritis. 2014; 11 (96): 84.

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