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EULAR 2017: Lilly's Taltz® (ixekizumab) Demonstrated No Progression or Minimal Progression of Radiographic Disease in Patients with Psoriatic Arthritis Through 52 Weeks

INDIANAPOLIS, June 16, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) announced today that the majority of patients with active psoriatic arthritis (PsA) treated with Taltz® (ixekizumab) exhibited either no progression or minimal progression of radiographic structural joint damage through 52 weeks of treatment. Detailed results from the extension period of the SPIRIT-P1 trial will be presented in an oral presentation today during the Annual European Congress of Rheumatology (EULAR) 2017, taking place June 14-17, in Madrid.

"Psoriatic arthritis is a chronic, progressive disease that if left untreated, can result in permanent, structural joint damage and impaired physical function," said Phillip Mease, M.D., Swedish Medical Center and University of Washington, Seattle, United States. "Results from the extension period of SPIRIT-P1 are encouraging and provide new information on the potential for Taltz, if approved, to address unmet needs of patients living with this challenging disease."

During the 24-week, double-blind period of the SPIRIT-P1 study, patients with active PsA who had never received a biologic disease-modifying antirheumatic drug (bDMARD) were treated with either 80 mg of Taltz once every two weeks or every four weeks (following a 160-mg starting dose), or adalimumab at the approved dose of 40 mg every two weeks or placebo. Adalimumab was employed as an active control in the SPIRIT-P1 study and was not powered for comparison with Taltz treatment groups. Following completion of the 24-week treatment period, patients were re-randomized to receive 80 mg of Taltz every two weeks or four weeks to evaluate response rates during the extension period through 52 weeks.

Patients treated with Taltz at both dosing regimens experienced either no progression or minimal radiographic progression of structural joint damage as measured by the change from baseline in the van der Heijde modified Total Sharp Score (mTSS) for PsA at 52 weeks. No progression or minimal radiographic progression of structural joint damage was also observed for patients who switched from placebo or adalimumab to either dosing regimen of Taltz after the 24-week treatment period.

During the extension period of SPIRIT-P1, the incidence of treatment-emergent adverse events was greater with Taltz treatment compared with placebo. The most common (≥4 percent) treatment-emergent adverse events observed in all patients treated with Taltz were nasopharyngitis and injection site reaction. These events are consistent with those reported in the Phase 3 studies of Taltz for the treatment of moderate-to-severe plaque psoriasis (UNCOVER 1, 2, 3).

"For patients living with psoriatic arthritis, it is important to work with a specialist to find a treatment that manages both the signs and symptoms of the disease, but also helps prevent further joint damage," said Dr. Lotus Mallbris, global brand development leader, Taltz, Eli Lilly and Company. "One year following the approval of Taltz for moderate-to-severe plaque psoriasis in the U.S., Canada and Europe, we are excited to present new data to rheumatologists from around the world at the Annual European Congress of Rheumatology (EULAR) 2017."

Lilly has filed a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for Taltz as a treatment of adult patients with active PsA. Taltz is approved for adult patients with active PsA in Japan. Submissions to other regulatory agencies around the world are expected later this year.

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 ($\geq 1\%$) 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[®]

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.

Taltz is also in Phase 3 trials for the treatment of radiographic and non-radiographic axial spondyloarthritis.

About the SPIRIT-P1 Study

SPIRIT-P1 is a Phase 3 randomized, active- and placebo-controlled study examining the effect of Taltz compared with placebo in patients with active PsA who are bDMARD-naïve. Patients were required to have an established diagnosis of psoriatic arthritis and active disease for at least six months. The trial included 417 patients (stratified 1:1:1:1 ratio for all treatment groups) with active PsA who had at least three tender and three swollen joints and the presence of at least one disease-related joint erosion of the hand or foot as seen on X-ray or a C-reactive protein (CRP) greater than 6 mg/L at screening. During the study, patients treated with Taltz received a starting dose of 160 mg administered subcutaneously (SC), as two 80-mg injections, followed by one of two dosing regimens: either 80 mg administered SC once every two weeks or 80 mg administered SC once every four weeks. Adalimumab at the approved dose of 40 mg SC and regimen of every other week was selected as the active control for comparison with placebo. The SPIRIT-P1 study will also evaluate the long-term efficacy and safety of Taltz in PsA for up to three years.

About Active Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive form of inflammatory arthritis that can cause swelling, stiffness and pain in and around the joints, nail changes and impaired physical function.¹ It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.² Typically, psoriatic arthritis affects peripheral joints in the arms and legs (elbows, wrists, hands and feet), but can also affect joints in the axial skeleton (spine, hips and shoulders).³ If left untreated, PsA can cause permanent joint damage.¹ Additionally, up to 30 percent of people with psoriasis also develop PsA.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 <http://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 About psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis>. Accessed June 7, 2017.

² What is psoriatic arthritis? Arthritis Foundation website. <http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php>. Accessed June 7, 2017.

³ Classification of psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis>. Accessed June 7, 2017.

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