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EULAR 2017: Lilly's Taltz® (ixekizumab) Demonstrated Significant Improvements in Disease Signs and Symptoms at 24 Weeks Among Patients with Active Psoriatic Arthritis Who Had Prior Inadequate Response or Intolerance to TNF Inhibitors

Taltz also demonstrated significant improvements in key secondary measures at 24 weeks

INDIANAPOLIS, June 15, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) announced today that patients with active psoriatic arthritis (PsA) who had inadequate response to one or two TNF inhibitors or were intolerant of TNF inhibitors treated with Taltz® (ixekizumab) achieved significant improvement in signs and symptoms of their disease at 24 weeks when compared to placebo. Detailed results of the SPIRIT-P2 study, a pivotal Phase 3 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. Results from the SPIRIT-P2 study were also recently published in *The Lancet* in May 2017.

"Psoriatic arthritis is a chronic, progressive disease that affects more than 37 million people worldwide, and can cause a range of signs and symptoms, including pain, swelling and stiffness of the joints that can lead to impaired physical function, as well as itchy and painful skin plaques," said Dr. Lotus Mallbris, global brand development leader, Taltz, Eli Lilly and Company. "We are pleased this data will be presented at the Annual European Congress of Rheumatology (EULAR) 2017, as it represents an invaluable opportunity to foster discussion among experts from around the world on the importance of new treatments for this debilitating disease."

Study Design
The SPIRIT-P2 study evaluated the safety and efficacy of Taltz (80 mg every four weeks or every two weeks, following a 160-mg starting dose) compared to placebo after 24 weeks in patients with active PsA who were previously treated with TNF inhibitors and had an inadequate response to one or two TNF inhibitors or were intolerant to TNF inhibitors. Patients were required to have a diagnosis of active PsA for at least six months and at least three tender and three swollen joints.

In this study, the primary endpoint was the percentage of patients achieving at least a 20 percent reduction in a composite measure of disease activity, as defined by the American College of Rheumatology (ACR20).[1] This study also evaluated secondary endpoints including ACR50 and ACR70, which represent 50 percent and 70 percent reductions in disease activity; improvement in physical function as assessed using the Health Assessment Questionnaire Disability Index (HAQ-DI); and improved skin clearance as measured by the Psoriasis Area Severity Index (PASI).

Taltz Demonstrated Significant Improvements in Disease Signs and Symptoms
Patients treated with either dosing regimen of Taltz demonstrated significant improvements at 24 weeks compared with placebo in disease activity of PsA.

At 24 weeks, patients achieved the following response rates:

- **ACR 20:** 53 percent of patients treated with Taltz every four weeks, 48 percent of patients treated with Taltz every two weeks and 19 percent of those treated with placebo ($p < 0.0001$).
- **ACR 50:** 35 percent of patients treated with Taltz every four weeks, 33 percent of patients treated with Taltz every two weeks and 5 percent of those treated with placebo ($p < 0.0001$).
- **ACR 70:** 22 percent of patients treated with Taltz every four weeks, 12 percent of patients treated with Taltz every two weeks and zero percent of those treated with placebo ($p < 0.0001$).

Reduced Disability in Physical Function, Significant Improvements in Skin Clearance
Patients treated with either dosing regimen of Taltz also experienced significant improvements compared with placebo in other key secondary measures, including physical function as assessed by the HAQ-DI and skin clearance in patients with at least 3 percent body surface area of skin involvement as measured by PASI 75, PASI 90 and PASI 100 at 12 weeks and 24 weeks. A PASI 75 score indicates at least a 75 percent reduction in a patient's plaque psoriasis from the patient's baseline assessment, while PASI 90 reflects a 90 percent reduction. PASI 100 represents a 100 percent reduction and reflects complete skin clearance.

"Many patients with psoriatic arthritis have tried a variety of therapies and have either lost response over time, had an inadequate response or been intolerant of therapy," said Associate Professor Peter Nash, lead author, University of Queensland, Queensland, Australia. "If approved, ixekizumab may provide physicians with a new option in this difficult-to-treat patient population."

The incidence of treatment-emergent adverse events was greater with Taltz treatment compared with placebo. The most common (≥5 percent in Taltz groups combined) treatment-emergent adverse events observed with Taltz treatment were injection site reaction, upper respiratory infection, nasopharyngitis and sinusitis. Serious adverse events and discontinuation rates due to adverse events were not significantly different between treatment groups.

Other warnings and precautions for Taltz include pre-treatment evaluation for tuberculosis, hypersensitivity reactions, inflammatory bowel disease and immunizations. See Important Safety Information below.

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 (> 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. Ixekizumab 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-P2 Study
SPIRIT-P2 is a Phase 3, randomized, double-blind, placebo-controlled study examining the effect of Taltz compared with placebo in patients with active PsA who were previously treated with TNF inhibitors and had an inadequate response to one or two TNF inhibitors or were intolerant to TNF inhibitors. The trial included 363 patients (randomized at a 1:1:1 ratio) with diagnosis of active PsA for at least six months and who had at least three tender and three swollen joints. 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. The SPIRIT-P2 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.[2] It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.[3] 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).[4] If left untreated, PsA can cause permanent joint damage.[2] Additionally, up to 30 percent of people with psoriasis also develop PsA.[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] A proposed revision to the ACR20: the hybrid measure of American College of Rheumatology response. *Arthritis & Rheumatism.* 2007;57:193-202. http://www.rheumatology.org/Portals/0/Files/A%20Proposed%20Revision%20to%20the%20ACR20.pdf. Accessed June 7, 2017.

[2] About psoriatic arthritis. National Psoriasis Foundation website. https://www.psoriasis.org/about-psoriatic-arthritis. Accessed June 7, 2017.

[3] 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.

[4] 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/eular-2017-lillys-taltz-ixekizumab-demonstrated-significant-improvements-in-disease-signs-and-symptoms-at-24-weeks-among-patients-with-active-psoriatic-arthritis-who-had-prior-inadequate-response-or-intolerance-to-tnf-inhibit-300474644.html

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