Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

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Refer to: Courtney Kasinger, ckasinger@lilly.com; 317-501-7056 (Lilly media)

Phil Johnson; johnson_philip_l@lilly.com; +1-317-655-6874 (Lilly investors)

Lilly's Taltz® (ixekizumab) Receives U.S. FDA Approval for the Treatment of Active Psoriatic Arthritis

- Psoriatic arthritis is the second approved indication for Taltz in the United States[1] -

INDIANAPOLIS, December 1, 2017 – Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved Taltz® (ixekizumab) injection 80 mg/mL for the treatment of adults with active psoriatic arthritis (PsA).[1] Taltz was first approved by the FDA in March 2016 for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[1]

"PsA is a chronic, progressive and painful form of inflammatory arthritis that impacts approximately 1.6 million Americans living with the disease," said Christi Shaw, president, Lilly Bio-Medicines. "We are proud to offer a new treatment option that can provide improvements in joint symptoms for these patients, further demonstrating Lilly's overall commitment to immunology."

Taltz may be administered alone or in combination with a conventional disease-modifying antirheumatic drug, such as methotrexate.[1] Taltz should not be used in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.[1] Taltz may increase the risk of infection.[1] Other warnings and precautions for Taltz include pre-treatment evaluation for tuberculosis, hypersensitivity reactions, inflammatory bowel disease and immunizations.[1] See Important Safety Information below.[1]

The efficacy and safety of Taltz was determined from findings from two randomized, double-blind, placebo-controlled Phase 3 studies – SPIRIT-P1 and SPIRIT-P2 – which included more than 670 adult patients with active PsA.[1] SPIRIT-P1 evaluated the safety and efficacy of Taltz compared to placebo in patients with active PsA who had never been treated with a biologic disease-modifying antirheumatic drug.[1] SPIRIT-P2 evaluated the safety and efficacy of Taltz compared to placebo in tumor necrosis factor inhibitor (TNFi)-experienced patients with active PsA who failed one or two TNF inhibitors.[1] Across both studies, patients were required to have a diagnosis of active PsA for at least six months and at least three tender and three swollen joints.[1] Non-responder imputation (NRI) methods were used. Inadequate responders (defined by blinded tender and swollen joint count criteria) at Week 16 received rescue therapy and were analyzed as non-responders.[1]

In studies of biologic-naïve and TNFi-experienced patients, the primary efficacy endpoint was the proportion of patients at 24 weeks achieving ACR20 response, which represents a 20 percent reduction in a composite measure of disease activity as defined by the American College of Rheumatology (ACR).[1] Results from both studies demonstrated that patients treated with Taltz achieved significant improvement in joint symptoms, as measured by ACR20, compared with placebo.[1] At 24 weeks, patients achieved ACR20 at the following response rates:

- SPIRIT-P1: 58 percent of patients treated with Taltz vs. 30 percent for placebo[1]
- SPIRIT-P2: 53 percent of patients treated with Taltz vs. 20 percent for placebo[1]

"For patients with PsA, treatment goals often include improvement in joint symptoms," said Philip Mease, M.D., Swedish Medical Center and University of Washington. "Based on the study results, Taltz can provide significant improvement in joint symptoms for patients who had never been treated with a biologic disease-modifying antirheumatic drug as well as patients who had inadequate response to one or two TNF inhibitors or were intolerant of TNF inhibitors."

Lilly will work with insurers, health systems and providers to ensure patients are able to access this treatment. Patients, physicians, pharmacists or other healthcare professionals with questions about Taltz should contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979) or visit www.lilly.com.

Indications and Usage

Taltz is approved for the treatment of adults with active psoriatic arthritis.[1] Taltz is also approved to treat adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[1]

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 ≤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 (≥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.

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About 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 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.[2] Psoriatic arthritis can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet).[2] If left untreated, PsA can cause permanent joint damage.[2] Up to 30 percent of people with psoriasis also develop PsA.[2]

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.[1] IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.[1] Taltz inhibits the release of pro-inflammatory cytokines and chemokines.[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.

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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 active 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 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.

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[1] Taltz Prescribing Information, 2017.
[2] Ritchlin C, et. al. Psoriatic Arthritis. *New England Journal of Medicine*. 2017;376:957-70.