Lilly Receives U.S. FDA Approval for Taltz® (ixekizumab) for the Treatment of Active Ankylosing Spondylitis (Radiographic Axial Spondyloarthritis)

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INDIANAPOLIS, Aug. 26, 2019 /PRNewswire/ -- 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 ankylosing spondylitis (AS), also known as radiographic axial spondyloarthritis (r-axSpA).

This is the third indication for Taltz, which was first approved by the FDA in March 2016 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and then approved by the FDA in December 2017 for the treatment of adults with active psoriatic arthritis.

"Ankylosing spondylitis is a challenging disease that can cause severe back pain and if left untreated, can significantly impact patient mobility," said Rebecca Morison, vice president, U.S. Immunology at Lilly. "We are excited to now offer Taltz as a treatment option for people in need of relief from the symptoms of AS. This approval further underscores Lilly's commitment to helping people living with rheumatic diseases."

Taltz may be administered alone or in combination with a conventional disease-modifying antirheumatic drug (e.g. sulfasalazine), corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and/or analgesics. Taltz should not be used in patients with a previous serious hypersensitivity, such as anaphylaxis, to ixekizumab or to any of the excipients. Taltz may increase the risk of infection. Other warnings and precautions for Taltz include pre-treatment evaluation for tuberculosis, hypersensitivity, inflammatory bowel disease, and immunizations. See Important Safety Information below.

AS is a 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] AS is estimated to impact approximately 1.6 million people in the U.S.[2]

"Having new treatment options for the ankylosing spondylitis community is truly encouraging," said Cassie Shafer, chief executive officer of the Spondylitis Association of America. "The ongoing focus to help people impacted by the disease will hopefully lead us to an eventual cure."

The efficacy and safety of Taltz in AS was demonstrated in two randomized, double-blind, placebo-controlled Phase 3 studies that included 657 adult patients with active AS: COAST-V in patients who are biologic disease-modifying antirheumatic drug (bDMARD)-naïve and COAST-W in patients who previously had an inadequate response or were intolerant to tumor necrosis factor (TNF) inhibitors.

In both studies, the primary efficacy endpoint was the proportion of patients at 16 weeks achieving Assessment of Spondyloarthritis International Society 40 (ASAS40) response compared to placebo. ASAS40 measures disease signs and symptoms such as pain, inflammation and function. The COAST clinical trial program includes the first and only registration trials in AS to achieve ASAS40 response at 16 weeks as a primary endpoint. Results from both studies demonstrated that patients treated with Taltz achieved statistically significant and clinically meaningful improvements in signs and symptoms, as defined by ASAS40 response, compared to placebo. At 16 weeks, patients achieved ASAS40 at the following response rates:

- COAST-V: 48 percent of patients treated with Taltz every four weeks versus 18 percent of patients treated with placebo ($p<0.0001$)
- COAST-W: 25 percent of patients treated with Taltz every four weeks versus 13 percent of patients treated with placebo ($p<0.05$)

Additionally, patients treated with Taltz demonstrated statistically significant improvements in key secondary endpoints in both studies, including the proportion of patients at 16 weeks achieving ASAS20 at the following response rates:

- COAST-V: 64 percent of patients treated with Taltz every four weeks versus 40 percent of patients treated with placebo ($p=0.0015$)
- COAST-W: 48 percent of patients treated with Taltz every four weeks versus 30 percent of patients treated with placebo ($p<0.01$)

Overall, the safety profile observed in patients with AS treated with Taltz is consistent with the safety profile in patients with psoriasis.

"Results from the Phase 3 clinical trial program in ankylosing spondylitis show that Taltz helped reduce pain and inflammation and improve function in patients who had never been treated with a bDMARD as well as those who previously failed TNF inhibitors," said Philip Mease, M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington. "This approval is an important milestone for patients and physicians who are looking for a much-needed alternative to address symptoms of AS."

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
Taltz is approved for the treatment of adults with active ankylosing spondylitis. Taltz is also approved for the treatment of adults with active psoriatic arthritis and 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 and ankylosing spondylitis. 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 80 mg Q2W group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis and in the Taltz Q4W group in ankylosing spondylitis trials (Crohn's disease 1.0% [2 patients], ulcerative colitis 0.5% [1 patient]) than in the placebo group (Crohn's disease 0.5% [1 patient], ulcerative colitis 0%). In the ankylosing spondylitis trials, serious events occurred in 1 patient in the Taltz group and 1 patient in the placebo group.

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 profiles observed in patients with psoriatic arthritis and ankylosing spondylitis were consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis.

Please see full Prescribing Information and Medication Guide for Taltz. 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 Lilly in Immunology
Lilly is bringing our heritage of championing groundbreaking, novel science to immunology and is driven to change what's possible for people living with autoimmune diseases. There are still significant unmet needs, as well as personal and societal costs, for people living with a variety of autoimmune diseases and our goal is to minimize the burden of disease. Lilly is investing in leading-edge clinical approaches across our immunology portfolio in hopes of transforming the autoimmune disease treatment experience. We've built a deep pipeline and are focused on advancing cutting edge science to find new treatments that offer meaningful improvements to support the people and the communities we serve.

About Eli Lilly and Company
Lilly is a global health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom. 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 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 August 8, 2019.
[2] Reveille, JD, Weisman, MH. The epidemiology of back pain, axial spondyloarthritis and HLA-B27 in the United States. *Am J Med Sci*. 2013;345(6):431-436.

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