Lilly's Taltz® (ixekizumab) Now Available in New, Citrate-Free Formulation to Reduce Injection Site Pain for Improved Patient Experience

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Since the medicine's first approval in 2016, nearly 130,000 people in the U.S. have been treated with Taltz

INDIANAPOLIS, Aug. 8, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the availability of a new, citrate-free formulation of Taltz® (ixekizumab) injection 80 mg/mL. The new formulation, which was recently approved by The U.S. Food and Drug Administration in May 2022, includes the same active ingredient as the original formulation. The new Taltz formulation significantly reduced injection site pain experienced by some people immediately following injection as shown by an 86% decrease in a visual analog scale (VAS) of pain versus the original formulation. Taltz is approved to treat adults and children six years and older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis, active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

"Taltz has long delivered effective treatment with a well-established safety profile that addresses symptoms for people living with plaque psoriasis, psoriatic arthritis, AS and nr-axSpA," said Ashley Diaz-Granados, vice president, U.S. Immunology at Lilly. "We're proud of our investment in research that keeps the patient experience at the center. This new formulation provides yet another reason to choose Taltz, and we look forward to introducing it to patients who have not yet tried Taltz and providing a seamless transition for those already enjoying the medicine's benefits."

Taltz citrate-free demonstrated a safety profile consistent with the original formulation. The safety information for Taltz can be found below.

Existing Taltz patients will not need a new prescription, nor should they experience a gap in their therapy. The new formulation is currently being shipped across the U.S. with anticipated broad availability for both new and existing Taltz patients by the end of the month. In the interim, the original formulation of Taltz continues to be available until it is replaced by the citrate-free formulation. The citrate-free formulation of Taltz was approved by the European Medicines Agency in December 2021 with several markets launching now and many more anticipated in the coming months.

"Today is an exciting milestone for the nearly 30 million people around the world who live with the challenging symptoms of these autoimmune diseases that affect the skin and joints," said April Armstrong, M.D., MPH, professor of dermatology and associate dean of clinical research, Keck School of Medicine at the University of Southern California. "In my six years of prescribing Taltz, I've seen firsthand the significant impact Taltz has had for patients across multiple indications. The availability of Taltz as a citrate-free formulation represents an important advance in patient care that will allow more patients to experience less injection-site pain."

Lilly is committed to improving experiences for people treated with Taltz, providing the same active ingredient in a new citrate-free formulation. Lilly's investment into patient-centric research is evident as Taltz has been studied in more than 10,000 people in clinical trials globally and has been available in most markets for more than five years.[1] In the U.S., more people living with psoriasis are treated with Taltz compared to any other IL-17A antagonist, adding to the nearly 130,000 people in the U.S. who have been treated with the medicine.[2]

To learn more about real success stories with Taltz, please visit Taltz.com.

IMPORTANT SAFETY INFORMATION FOR TALTZ

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 adult 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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. 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
Patients treated with Taltz may be at an increased risk of inflammatory bowel disease. In clinical trials, Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group than the placebo group. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease and if IBD occurs, discontinue Taltz and initiate appropriate medical management.

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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis were consistent with the safety profile in adult patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis and conjunctivitis, influenza, and urticaria in pediatric psoriasis.

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 the Citrate-Free Injection Pain Study
The citrate-free injection pain study (N=70) was a subject-blind, randomized, crossover study in healthy participants ages 18-75 years to determine injection site pain differences between Taltz citrate-free formulation compared to the original formulation of Taltz. The primary endpoint, pain intensity on injection, was measured by the Visual Analog Scale (VAS) of pain 0-100mm.[3]

About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn.

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Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Taltz as a treatment for people with moderate to severe plaque psoriasis, active psoriatic arthritis, active ankylosing spondylitis and active non-radiographic axial spondyloarthritis and other conditions and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that future study results will be consistent with study results to date. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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. Data on file. Lilly USA, LLC. DOF-IX-US-0310
2. Data on file. Lilly USA, LLC. DOF-IX-US-0307
3. Chabra S, Gill BJ, Gallo G, et al. Ixekizumab citrate-free formulation: results from two clinical trials. *Adv Ther.* 2022;Epub (Incl Suppl Inf):1-11, 1-4. https://doi.org/10.1007/s12325-022-02126-0

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