New Data at EADV 2020 Confirm Taltz® (ixekizumab) Demonstrates Sustained Long-Term Efficacy in Patients with Psoriasis and Psoriatic Arthritis

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- Long-term and post-hoc analysis data show continued efficacy of Taltz in treating challenging body areas, including scalp, nails, palms and soles -

INDIANAPOLIS, Oct. 29, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will share new Taltz® (ixekizumab) data from multiple long-term and post-hoc analyses that indicate sustained efficacy in patients with psoriasis and psoriatic arthritis. Notably, Lilly will share results from the extension period of UNCOVER-3 demonstrating five-year sustained efficacy of Taltz in patients with psoriasis in treating challenging body areas, such as the scalp, nails, palms and soles. These studies will be presented at the 29th annual European Academy of Dermatology and Venereology (EADV) Congress, taking place virtually October 29-31, 2020.

"Finding an effective long-term treatment option that can clear hard-to-treat body areas that patients find particularly burdensome, such as the scalp and nails, is one of the most important considerations when treating psoriasis," said Andrew Blauvelt, M.D., M.B.A., a board-certified dermatologist, President of Oregon Medical Research Center, and lead author of the UNCOVER-3 five-year disclosure. "These data demonstrate that Taltz was able to provide sustained responses in these challenging skin areas and should help physicians make informed treatment decisions for their psoriasis patients."

Taltz psoriasis data from UNCOVER-3

Taltz demonstrated sustained efficacy in adult psoriasis patients with baseline scalp, nail and palmoplantar (skin on the palms of the hands and soles of the feet) involvement with the following results at five years (Week 264):

- **Complete clearance:** With Taltz, 83%, 73% and 89% of patients reported complete clearance in scalp, nail and palmoplantar psoriasis, respectively.
- **Mean percent improvements:** Patients reported mean percent improvements of 89%, 88% and 95% from baseline in scalp, nail and palmoplantar psoriasis, respectively.

In the UNCOVER-3 study, adult patients were initially randomized across four treatment arms to receive placebo, Taltz 80 mg every two weeks or every four weeks following an initial dose of Taltz 160 mg, or etanercept (marketed as Enbrel®) 50 mg twice weekly in the 12-week induction period. At Week 12, eligible patients entered the long-term extension period and received the FDA-approved dose of Taltz for psoriasis – 80 mg every four weeks. This analysis examines the patients who received the label-approved dose of Taltz. For these patients, Psoriasis Scalp Severity Index (PSSI), the Nail Psoriasis Severity Index (NAPSI) and/or the Palmoplantar Psoriasis Area and Severity Index (PPASI) were assessed through 264 weeks.

In the UNCOVER-3 study, the safety profile of Taltz over five years remained consistent with previous reports, with no unexpected safety outcomes and no new adverse events. The majority of the treatment–emergent adverse events (TEAEs) were mild to moderate in nature with nasopharyngitis and upper respiratory tract infection the most frequently reported.

Additional Taltz data in psoriatic arthritis

Lilly will also be highlighting notable results from two studies in psoriatic arthritis. In the SPIRIT-P2 study, Taltz demonstrated persistent clearance of nail and skin psoriasis plaques in patients with active psoriatic arthritis, as measured by NAPSI, Psoriasis Area and Severity Index (PASI) and static Physician's Global Assessment (sPGA) responses, for up to three years in patients with prior inadequate response or intolerance to one or two tumor necrosis factor inhibitors (TNFi).

In a post-hoc analysis of patients with nail psoriasis at baseline from the SPIRIT-H2H study of TNFi treatment-naïve patients with both active psoriatic arthritis and active psoriasis, 83% of patients treated with Taltz maintained complete resolution of nail psoriasis up to 52 weeks vs. 72% of patients treated with adalimumab (marketed as Humira®).

In both studies, the safety profile of Taltz was consistent with previously reported results and no unexpected safety signals were found.

"These long-term studies provide healthcare providers and people living with psoriasis and psoriatic arthritis valuable information regarding the effectiveness of Taltz in helping patients achieve and sustain complete skin clearance, even in these particularly burdensome skin areas," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "The data presented across Lilly's dermatology portfolio at this year's virtual EADV Congress reflect our commitment to continuously improving the standard of care for the treatment of psoriasis and other autoimmune conditions."

More than 170,000 patients have been treated with Taltz worldwide since launch, giving healthcare providers confidence in making informed prescribing decisions for patients with psoriasis and psoriatic arthritis, as well as in other approved conditions including ankylosing spondylitis and non-radiographic axial spondyloarthritis.

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and for the treatment of adults with active psoriatic arthritis, active ankylosing spondylitis, or active non-radiographic axial spondyloarthritis with objective signs of inflammation.

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 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 Moderate to Severe Plaque Psoriasis
Psoriasis is a chronic, immune disease that affects the skin. It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate to severe plaque psoriasis. The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells. Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease and experience negative impact on their quality of life.

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. It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons. PsA can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet). If left untreated, PsA can cause permanent joint damage. Up to 30 percent of people with psoriasis also develop PsA.

About Lilly in Dermatology
By following the science through uncharted territory, we continue Lilly's legacy of delivering innovative medicines that address unmet needs and have significant impacts on people's lives around the world. Skin-related diseases are more than skin deep. We understand the devastating impact this can have on people's lives. At Lilly, we are relentlessly pursuing a robust dermatology pipeline to provide innovative, patient-centered solutions so patients with skin-related diseases can aspire to live life without limitations.

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/news. 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 patients with psoriasis or 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 future study results will be consistent with the results to date or 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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