Taltz® Delivers More Cumulative Days with Completely Clear Skin for Adults with Psoriasis Compared to Seven Other Biologics in Novel Network Meta-Analysis

April 23, 2021

- Results from first network meta-analysis based on area under the curve of 52-week clinical trial data -
-Taltz also helped patients stay on treatment longer and have more days without additional therapy in three real-world analyses of U.S. claims data -

INDIANAPOLIS, April 23, 2021 /PRNewswire/ -- Through clinical trial meta-analysis and real-world evidence, Eli Lilly and Company's (NYSE: LLY) Taltz® (ixekizumab) demonstrated greater success in key measured treatment outcomes compared to other biologics in adults with moderate to severe plaque psoriasis. In the first one-year network meta-analysis based on area under the curve, Taltz showed numerically greater cumulative benefits on completely clear skin over one year compared to seven other biologics, as measured by Psoriasis Area Severity Index (PASI) 100. In three real-world analyses of U.S. claims data ranging from one to three years, patients treated with Taltz stayed on treatment longer, were more adherent to the prescription and had more days on monotherapy compared to the other biologics studied. These results are being presented virtually at the American Academy of Dermatology's Virtual Meeting Experience (AAD VMX), April 23-25, 2021.

"We are thrilled to present our novel analysis of clinical trial data showing Taltz provided numerically more cumulative days of completely clear skin for adult patients suffering from psoriasis, compared to seven other biologic options. This analysis reinforces our clinical trial findings which previously showed that Taltz provides rapid and sustained improvement of psoriasis. We're pleased to give dermatologists additional insights about Taltz that can help them make important treatment decisions for patients who seek totally clear skin," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "At Lilly, it's equally important that our research goes beyond controlled clinical trials to include real-world analyses that provide clarity for dermatologists around how patients manage their psoriasis and respond to treatment in everyday life."

Taltz Provided Patients with Longest-Lasting Complete Skin Clearance over a One-Year Period

In the network meta-analysis to assess the cumulative clinical benefits of biologics in psoriasis, using PASI 100 to measure the early and sustained effect of biologic medications approved for psoriasis over one year, Taltz offered patients with psoriasis the greatest number of cumulative days of completely clear skin compared to adalimumab, brodalumab, etanercept, guselkumab, risankizumab, secukinumab and ustekinumab. In this analysis, Taltz showed one to 18 more cumulative weeks of completely clear skin over one year compared to these seven other biologics.

Taltz provided patients with a total of 159 cumulative days (95% credible interval, 147.4-170.0 days), or 23 weeks of completely clear skin (PASI 100), which translates into a patient having completely clear skin for approximately 44% of the year compared to: risankizumab (152 days [141.6-162.0 days], or 22 weeks and 42% of the year); brodalumab (138 days [119.0-157.2 days], 20 weeks and 38% of the year); guselkumab (131 days, [120.8-141.6 days], 19 weeks and 36% of the year); secukinumab (119 days [111.7-127.0 days], or 17 weeks and 33% of the year); ustekinumab (74 days [63.3-84.4 days], or 11 weeks and 20% of the year), adalimumab (67 days [55.7-77.9 days], or 10 weeks and 18% of the year) and etanercept (32 days [23.7-39.7 days], or 5 weeks and 9% of the year). For methodology, see "About the Studies" section below.

"As a dermatologist, I am excited to have insight about the one-year cumulative clinical benefit of biologic treatments available to treat psoriasis," said Mark G. Lebwohl, M.D., Dean for Clinical Therapeutics at the Icahn School of Medicine at Mount Sinai, and lead author of this analysis. "When discussing treatment goals, at the top of the list for many patients is completely clear skin that lasts over time. The analysis shows that people taking Taltz have about 160 days of completely clear skin a year – more than any other biologic included in this analysis."

Taltz Helped Patients Stay on Prescribed Treatment, and to Avoid Additional Psoriasis Therapy Significantly Longer, Compared to Secukinumab, Ustekinumab, Adalimumab and Etanercept

People with psoriasis taking Taltz achieved greater success taking medication as prescribed (adherence) and staying on medication for the prescribed duration (persistence), without needing additional medications (monotherapy), compared to those taking secukinumab, ustekinumab, adalimumab and etanercept up to three years. Patients on Taltz stayed on treatment an observed median of nearly 22 weeks longer vs. all other biologics pooled (414 vs. 259 days, [59 vs. 37 weeks], $p<0.001$) and approximately 11 to 34 weeks longer vs. individual treatments: secukinumab (335 days [48 weeks]), adalimumab (301 days [43 weeks]), etanercept (181 days [26 weeks]) and ustekinumab (176 days [25 weeks]). Compared with the pooled set of other biologics where patients stayed on prescription for less than half of the year (45.7%), patients on Taltz took treatment as prescribed for over half of the year (53.2%), as measured by proportion of days covered (PDC) by prescribed treatment ($p<0.001$). Patients taking Taltz also experienced more time (52.7% of the year) on monotherapy compared to the pooled set of other biologics (44.8% of the year) ($p<0.001$). For methodology, see "About the Studies" section below.

Patients on Taltz Took Treatment as Prescribed Nearly Eight Weeks More Than Guselkumab, Despite More Frequent Dosing

Compared to guselkumab, patients with psoriasis on Taltz adhered to treatment for nearly eight weeks more time (Taltz: median of 272 days or 39 weeks [PDC=0.75]; guselkumab: 219 days or 31 weeks [PDC=0.60], $p=0.001$) and had approximately six weeks more time on monotherapy (Taltz: median of 247 days or 35 weeks [PDC=0.68]; guselkumab: 202 days or 29 weeks [PDC=0.55], $p=0.002$) over one year. Among those patients who required additional psoriasis therapies, the need for systemic medication was similar for patients taking Taltz or guselkumab over the year. For methodology, see "About the Studies" section below.

Patients on Taltz with Prior Biologic Use Were More Likely to Continue Treatment as Prescribed Compared to Secukinumab

Among participants who had previously used a biologic, patients with psoriasis treated with Taltz were more likely to be "highly adherent," which was

measured by more than 80% of days where they took treatments as prescribed (Taltz: 42.0% vs. secukinumab: 35.0%, p=0.019). Taltz was associated with 25% lower risk of switching treatments, 20% lower risk of stopping treatment before the end of the prescribed duration (non-persistence), 19% lower risk of discontinuing treatment, and 36% higher odds of taking treatment as prescribed (adherence) than secukinumab. For methodology, see "About the Studies" section below.

"These new data reveal real-world evidence showing that patients with psoriasis who were treated with ixekizumab stay on treatment longer compared to several other biologics, regardless of past biologic experience," said Andrew Blauvelt, M.D., M.B.A., a board-certified dermatologist, president of Oregon Medical Research Center, and lead author of these analyses. "The ability to stay on a biologic over time correlates with treatment success, whereas switching biologic therapies in practice is associated with more time, healthcare costs and patient dissatisfaction. These data demonstrate high treatment persistence with ixekizumab, and thus provide important data for dermatologists to consider when choosing a biologic therapy for their psoriasis patients."

More than 175,000 patients have been treated with Taltz worldwide since launch, giving healthcare providers confidence in making informed prescribing decisions for patients with moderate to severe plaque psoriasis and psoriatic arthritis, as well as in other approved conditions including ankylosing spondylitis and non-radiographic axial spondyloarthritis.

About The Studies

- **Cumulative Clinical Benefits of Biologic Treatments for Psoriasis over 1 Year**
  The network meta-analysis used data from published Phase 3 clinical trials for Taltz, adalimumab, brodalumab, etanercept, guselkumab, infliximab, risankizumab, secukinumab and ustekinumab to evaluate the cumulative clinical benefits of psoriasis treatments. The area under-the-curve (AUC) method was used to measure total cumulative benefit, which takes into account the early effect seen from week 0 and sustained effect through week 52, using four-week increments, whereas traditional analyses use one-time measurements at week 12, 16 or 52. The cumulative benefits for each treatment were normalized as a percentage of maximum possible AUC. Cumulative days at PASI 90 and PASI 100 were calculated by multiplying normalized AUC by the study duration. Sensitivity analysis was conducted using the same clinical trials with 48-week data.

- **Ixekizumab Demonstrates Greater Medication Adherence, Persistence and Longer Monotherapy Duration than Secukinumab, Ustekinumab, Adalimumab and Etanercept up to 3 Years in the Treatment of Psoriasis: Real-World Results from IBM MarketScan® Database**
  Using claims from the IBM MarketScan Database from January 1, 2016, to April 30, 2020, adherence, persistence and monotherapy rates were evaluated for 7,797 adult patients with psoriasis prescribed Taltz (n=742), secukinumab (n=1,027), ustekinumab (n=1,912), adalimumab (n=3,592), or etanercept (n=524). Patients had ≥6 months pre-index and ≥1-year post-index continuous enrollment and were followed up to three years after their first prescription. Treatment comparisons were based on balanced samples after inverse probability of treatment weighting.

- **Real-World Comparison of Monotherapy and Concomitant Medication Use with Biologic Therapies for Psoriasis: Ixekizumab vs. Guselkumab**
  Using claims from the IBM MarketScan Database from July 1, 2017, through December 31, 2018, monotherapy and additional medication usage were compared between Taltz and guselkumab, the first IL-23 to have a large enough sample size to do a robust analysis. Adult patients with psoriasis with ≥1 prescription claim for Taltz (n=676) or guselkumab (n=739) were included. The first prescription claim was the index date; patients had continuous enrollment for ≥6 months pre-index and ≥1-year post-index. Treatment comparisons were based on balanced samples after inverse probability of treatment weighting.

- **Comparison of Long-Term Treatment Patterns between Ixekizumab and Secukinumab Users among Biologic-experienced Psoriasis Patients**
  Using claims from the IBM MarketScan Database from March 1, 2016, to October 31, 2019, long-term treatment patterns were compared among patients previously treated with a biologic who were then treated with Taltz (n=411) or secukinumab (n=780). The index date was the date of first Taltz or secukinumab claim. Adults with psoriasis with ≥1 prior biologic prescription six months pre-index and 18 months post-index period continuous enrollment with medical and pharmacy benefits were included in this study. Treatment comparisons were based on balanced samples after inverse probability of treatment weighting.

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 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 and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of research, 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.

Refer to: Marlo Scott; scott_marlo@lilly.com; 317-407-8879 (media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (investors)

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