New Head-to-Head Data Show Taltz® (ixekizumab) Superiority versus TREMFYA® (guselkumab) in People with Moderate to Severe Plaque Psoriasis

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-Taltz met the primary endpoint of the IXORA-R study, with 41.3 percent of patients taking Taltz achieving complete skin clearance as measured by PASI 100 at Week 12 versus 24.9 percent of patients taking TREMFYA

-Taltz also met all major secondary endpoints up to Week 12

INDIANAPOLIS, Oct. 3, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today presented detailed data at the 5th Annual Maui Derm NP+PA Fall meeting from the Phase 4 IXORA-R study, the first head-to-head (H2H) study between an IL-17A inhibitor and an IL-23/p19 inhibitor using the Psoriasis Area Severity Index (PASI) 100 score as the primary endpoint. Taltz met the primary endpoint of superiority vs. TREMFYA in the proportion of patients with moderate to severe plaque psoriasis achieving complete skin clearance as measured by PASI 100 at Week 12, as well as key secondary endpoints. The study is ongoing through Week 24.

"Healthcare providers and patients value speed of response when evaluating treatment options for moderate to severe plaque psoriasis," said lead study investigator Andrew Blauvelt, M.D., M.B.A., dermatologist and president of Oregon Medical Research Center in Portland, OR. "The results from the IXORA-R study demonstrate that Taltz was effective in helping more patients achieve completely clear skin by Week 12, with a 50 percent improvement in skin plaques seen as early as Week 1."

The primary endpoint of the study was superiority for Taltz compared to TREMFYA in the proportion of patients achieving complete skin clearance as measured by PASI 100 at Week 12. Key secondary endpoints included superiority over TREMFYA in the proportion of patients achieving PASI 75 at Week 2, PASI 90 at Weeks 4 and 8, PASI 100 at Weeks 4, 8 and 24, static Physician's Global Assessment (sPGA) 0 at Week 12 and PASI 50 at Week 1.

Patients treated with Taltz demonstrated statistically significantly higher improvements than those treated with TREMFYA as measured by PASI 100 at Week 12 (41.3 percent versus 24.9 percent, P<0.001). Additionally, all major secondary endpoints up to Week 12 were achieved (P<0.001).

"As new medicines become available for people living with psoriasis, there's an increasing need to directly compare the efficacy and safety of these treatments to help healthcare providers and patients make informed treatment decisions," said Rhonda Pacheco, Pharm.D., global brand development leader for immunology at Lilly. "These results demonstrate that Taltz can provide high levels of skin clearance early in treatment for people with psoriasis."

A total of 1,027 patients with moderate to severe plaque psoriasis were enrolled in the study to evaluate the efficacy and safety of Taltz compared to TREMFYA. Participants were randomized to receive Taltz or TREMFYA at the approved dose for a total of 24 weeks, with the primary analysis conducted at 12 weeks.

In IXORA-R, the safety profiles of Taltz and TREMFYA were consistent with those previously reported for both treatments. As the IXORA-R study is ongoing, not all data will be presented at this meeting to prevent unblinding for investigators and participants. Lilly plans to share results on the remaining key secondary endpoint of proportion of patients achieving PASI 100 at 24 weeks in 2020.

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Taltz is also approved for the treatment of adults with active psoriatic arthritis and active ankylosing spondylitis.

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 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 accompanying Prescribing Information **and** Medication Guide. **Please 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.[1] 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.[1]

About Moderate to Severe Plaque Psoriasis
Psoriasis is a chronic, immune disease that affects the skin.[2] 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.[1,3] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[1] 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.[1]

About the IXORA-R Study
IXORA-R is a Phase 4, multicenter, randomized, blinded, parallel-group study comparing the efficacy and safety of Taltz versus TREMFYA in people living with moderate to severe plaque psoriasis. The primary endpoint of the study was the proportion of patients achieving PASI 100 response at Week 12. The major secondary endpoints include the proportion of patients achieving PASI 75 at Week 2, PASI 90 at Weeks 4 and 8, PASI 100 at Weeks 4, 8 and 24, static Physician's Global Assessment (sPGA) 0 at Week 12 and PASI 50 at Week 1.

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 patients with moderate to severe plaque psoriasis, 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, 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 undertake no duty to update forward-looking statements to reflect events after the date of this release.

[1] Taltz Prescribing Information, 2019.

[2] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed September, 2019.

[3] Skin conditions by the numbers. American Academy of Dermatology website. https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed September, 2019.

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