Lilly Announces Superiority of Taltz® (ixekizumab) versus TREMFYA® (guselkumab) in Delivering Total Skin Clearance at Week 12 in Topline Results from Head-to-Head (IXORA-R) Trial in People Living with Moderate to Severe Plaque Psoriasis

August 13, 2019

- IXORA-R is the first Phase 4 head-to-head study comparing efficacy between an IL-17A inhibitor and an IL-23/p19 inhibitor using PASI 100 as the primary endpoint -

INDIANAPOLIS, Aug. 13, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today Taltz® (ixekizumab) met the primary and all major secondary endpoints up to week 12 in the Phase 4 IXORA-R study, which evaluated the efficacy and safety of Taltz versus TREMFYA® (guselkumab) in people living with moderate to severe plaque psoriasis (PsO). The IXORA-R trial is the first completed head-to-head (H2H) trial between an IL-17A inhibitor and an IL-23/p19 inhibitor using the Psoriasis Area Severity Index (PASI) 100 score as the primary endpoint.

At 12 weeks, Taltz met the primary endpoint by demonstrating superiority in the proportion of patients achieving complete skin clearance compared to TREMFYA as measured by PASI 100. In addition, Taltz met all major secondary endpoints up to week 12, which include 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 and 8, static Physician's Global Assessment (sPGA) 0 at Week 12 and PASI 50 at Week 1. Lilly plans to share results on the remaining key secondary endpoint of proportion of patients achieving PASI 100 at 24 weeks in 2020.

"Completely clear skin and rapid relief of symptoms are possible for many people living with moderate to severe plaque psoriasis, and should be two topics dermatologists discuss with their patients," said Andrew Blauvelt, M.D., M.B.A., dermatologist and president of Oregon Medical Research Center in Portland, OR. "Head-to-head data like these are important and will help inform individual treatment goal discussions between healthcare providers and their patients."

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 (160 mg at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks) or TREMFYA (100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter) for a total of 24 weeks, with the primary analysis conducted at 12 weeks.

"Lilly's goal is to raise the treatment bar for people living with psoriasis," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "And research shows that patients want clear skin and rapid improvements. We're pleased to see that Taltz helped more people achieve 100 percent skin clearance compared to TREMFYA at week 12. These positive results reinforce that Taltz is an important treatment option for people with this disease."

In IXORA-R, the safety profile of Taltz was consistent with previously reported results. No new safety signals were detected.

Lilly plans to submit detailed data from the IXORA-R study for disclosure at scientific meetings and in peer-reviewed journals.

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved to treat 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.

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. 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
Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease.

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 profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please see accompanying Prescribing Information **and** Medication Guide. **Please see** Instructions for Use **included with the device.**

IX HCP ISI 01DEC2017

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 50 at Week 1; PASI 75 at Week 2; PASI 90 at Weeks 4 and 8; and PASI 100 at Weeks 4, 8 and 24; as well as the proportion of patients achieving a Static Physician Global Assessment (sPGA) score of 0 at Week 12.

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 achieve its primary study endpoints or receive regulatory approvals or that Taltz will continue to 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] Taltz Prescribing Information, 2018.
[2] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed July, 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 July, 2019.

Refer to: Jackie Shelton; sheltonj@lilly.com; 317-719-5928 (media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (investors)

View original content to download multimedia:http://www.prnewswire.com/news-releases/lilly-announces-superiority-of-taltz-ixekizumab-versus-tremfya-guselkumab-in-delivering-total-skin-clearance-at-week-12-in-topline-results-from-head-to-head-ixora-r-trial-in-people-living-with-moderate-to-severe-plaque-pso-300900135.html

SOURCE Eli Lilly and Company