Lilly Announces Positive Top-Line Results for Taltz® (ixekizumab) vs. Humira® (adalimumab) in a Head-to-Head (SPIRIT-H2H) Superiority Study in Patients with Active Psoriatic Arthritis

December 17, 2018

INDIANAPOLIS, Dec. 17, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today Taltz® (ixekizumab) met the primary and all major secondary endpoints in the Phase 3b/4 SPIRIT-H2H study, which evaluated the efficacy and safety of Taltz versus Humira® (adalimumab) in patients with active psoriatic arthritis (PsA) who are biologic disease-modifying anti-rheumatic drug (DMARD)-naive. The SPIRIT-H2H trial is the first completed large head-to-head (H2H) superiority study in active PsA. This open-label, randomized, controlled trial is the first and only H2H study that utilizes on-label dosing for both Taltz and Humira and includes concomitant conventional DMARDs.

At 24 weeks, patients treated with Taltz met the primary endpoint by demonstrating superiority in improving the signs and symptoms of active PsA compared to Humira as measured by the proportion of patients simultaneously achieving at least a 50-percent reduction in disease activity, as defined by the American College of Rheumatology (ACR50), as well as complete skin clearance as measured by the Psoriasis Area and Severity Index (PASI100). In addition, Taltz met the major secondary endpoints.

"The positive results from the SPIRIT-H2H trial reinforce that Taltz effectively treats the debilitating joint signs and symptoms of active psoriatic arthritis, while also providing skin clearance," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "These results provide evidence that Taltz can be used as a first-line biologic treatment for patients with active psoriatic arthritis."

A total of 566 active PsA patients were enrolled in the study to evaluate the efficacy and safety of Taltz compared to Humira. Patients with active PsA were randomized to receive Taltz at the approved dose (160-mg starting dose followed by 80 mg every four weeks), or Humira (40 mg every two weeks) for a total of 52 weeks, with the primary analysis conducted at 24 weeks. Patients meeting criteria for moderate-to-severe plaque psoriasis received the approved dose of Taltz (160-mg starting dose followed by 80 mg every two weeks from Week 2 to Week 12 and every four weeks thereafter) or Humira (80-mg starting dose followed by 40 mg every two weeks, one week after the initial dose).

"In the SPIRIT-H2H trial, Taltz demonstrated superiority in improving active psoriatic arthritis compared to Humira," said Philip Mease, M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington. "This study will help raise awareness and better inform conversations between patients and their healthcare providers about treatment options for active psoriatic arthritis."

In SPIRIT-H2H, 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 SPIRIT-H2H study for disclosure at scientific meetings and in peer-reviewed journals in 2019.

Lilly unites caring with discovery to create medicines that make life better for people living with immune-mediated diseases.

About the SPIRIT-H2H study
SPIRIT H2H study is a Phase 3b/4, multicenter, randomized, open-label, parallel-group study with blinded outcomes assessments evaluating the efficacy and safety of Taltz versus Humira in patients with PsA who are biologic DMARD-naive during a 52-week treatment period. The primary endpoint of the study was the simultaneous achievement of ACR50 and PASI100 response at Week 24. This primary endpoint is an innovative approach that comprehensively measures clinically meaningful improvements across multiple domains of PsA. The major secondary endpoints were the demonstration of non-inferiority in ACR50 and superiority in PASI100 in Taltz compared to Humira. Patients with active PsA and plaque psoriasis with a body surface area involvement of at least three percent, who had inadequate response to at least one conventional DMARD, were enrolled in the study.

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

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.**

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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 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.[1] It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.[1] PsA can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet).[1] If left untreated, PsA can cause permanent joint damage. Up to 30 percent of people with psoriasis also develop PsA.[1]

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to 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 www.lilly.com and www.lilly.com/newsroom/social-channels. 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) in patients with active 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, 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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[1] Ritchlin C, et. al. Psoriatic Arthritis. New England Journal of Medicine. 2017;376:957-70.

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