Lilly Presents Positive Results for Taltz® (ixekizumab) vs. Humira® (adalimumab) in a Head-to-Head (SPIRIT-H2H) Superiority Study in Patients with Active Psoriatic Arthritis at the European Congress of Rheumatology

June 14, 2019

INDIANAPOLIS, June 14, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the company will present positive findings from the Phase 3b/4 SPIRIT-Head-to-Head (H2H) study in patients with active psoriatic arthritis (PsA) as a late-breaking abstract at the European Congress of Rheumatology (EULAR) in Madrid, Spain on June 15.

The assessor-blinded, randomized, controlled trial is the first and only H2H study that utilizes on-label dosing for both Taltz® (ixekizumab) and Humira® (adalimumab) and allows inclusion of concomitant conventional DMARDs. Topline results from the study, which demonstrated Taltz met the primary and all major secondary endpoints, were announced in December 2018.

"In the SPIRIT-H2H trial, Taltz demonstrated effectiveness in improving the signs and symptoms of active psoriatic arthritis," said Philip Mease, M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington. "Head-to-head data like these are significant and help inform treatment decisions. This study underscores that Taltz is an important option for healthcare providers to consider for their patients."

The primary endpoint of the study was superiority for Taltz compared to Humira in the proportion of patients who simultaneously achieved a reduction by at least 50 percent in disease activity as defined by the American College of Rheumatology (ACR50) and complete skin clearance as measured by the Psoriasis Area and Severity Index (PASI 100). Key secondary endpoints included non-inferiority in the proportion of patients who achieved ACR50 and superiority in the proportion of patients who achieved PASI 100.

"For patients with active psoriatic arthritis, it's important to find a treatment that is effective and consistent in alleviating the debilitating joint symptoms, while also improving skin clearance," said Christi Shaw, president, Lilly Bio-Medicines. "We're pleased to share the full results of SPIRIT-H2H, which demonstrate that Taltz was more effective than Humira in simultaneously achieving both joint and skin responses after 24 weeks of treatment."

A total of 566 patients with active PsA were enrolled in the SPIRIT-H2H study. Patients were randomized to receive Taltz (n=234) or Humira (n=231) at the approved dose for PsA for a total of 52 weeks, with the primary analysis conducted at 24 weeks. PsA patients who also met the study criteria for moderate- to severe plaque psoriasis received Taltz (n=49) or Humira (n=52) at the approved dose for psoriasis.

At 24 weeks, the proportion of patients achieving both a reduction by at least 50 percent in disease activity as defined by ACR50 as well as complete skin clearance as measured by PASI 100, was significantly higher for Taltz (36 percent) than for Humira (28 percent) (P<.05).

Taltz also met the key secondary endpoints, including non-inferiority compared to Humira for the percentage of patients achieving ACR50 (51% vs. 47%) (95% CI [-4.3% , 12.1%]) (for noninferiority with -12.0% margin) and superiority compared to Humira for the percentage of patients achieving PASI 100 (60% vs. 47%) (P=.001).

In SPIRIT-H2H, the safety profile of Taltz was consistent with previously reported results. The most common adverse reactions were mild to moderate in severity, and included infections (36.0% for Taltz vs. 30.7% for Humira), injection site reactions (9.5% for Taltz vs. 3.2% for Humira), allergic/hypersensitivity reactions (2.5% for Taltz vs. 3.9% for Humira) and cerebrocardiovascular events (1.1% for Taltz vs. 1.8% for Humira). No new safety signals were detected.

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.[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 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.[2] It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.[2] PsA can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet).2 If left untreated, PsA can cause permanent joint damage. Up to 30 percent of people with psoriasis also develop PsA.[2]

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.

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 healthcare 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 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) as a treatment for 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 undertake no duty to update forward-looking statements to reflect events after the date of this release.

[1] Taltz Prescribing Information, 2018.
[2] Ritchlin C, et. al. Psoriatic Arthritis. New England Journal of Medicine. 2017;376:957-70.

Refer to: Michael McDougall, mcdougall_michael@lilly.com; 647-226-3066 (media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (investors)

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