ACR 2019: Lilly Presents 52-Week Head-to-Head (SPIRIT-H2H) Data from Taltz® (ixekizumab) Versus Humira® (adalimumab) Trial in Psoriatic Arthritis

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Taltz demonstrated sustained effect when compared to Humira through 52 weeks in patients with active psoriatic arthritis

INDIANAPOLIS, Nov. 12, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the 52-week results from the Phase 3b/4 SPIRIT-Head-to-Head (H2H) study of Taltz® (ixekizumab) versus Humira® (adalimumab) in biologic-naïve patients with active psoriatic arthritis (PsA). The results are being presented as a late-breaking oral presentation at the American College of Rheumatology (ACR)/Association of Rheumatology Professionals (ARP) Annual Meeting in Atlanta.

Taltz met the primary and all major secondary endpoints of the study. Taltz was superior to Humira at Week 24 as measured by the primary endpoint of simultaneous achievement of 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). At Week 52, 39 percent of patients treated with Taltz had sustained simultaneous joint and skin improvement (ACR50 and PASI 100), compared with 26 percent of patients treated with Humira.

"We currently have limited data on comparisons of the safety and efficacy of biologic therapies used for the treatment of psoriatic arthritis," said Josef Smolen, M.D., professor of medicine at the Medical University of Vienna, Austria and lead author of the abstract. "The 24-week data from the SPIRIT-H2H trial demonstrated that ixekizumab, when compared to adalimumab, provided superior efficacy on the pre-specified combined endpoint of improvement in joint and skin symptoms. Ixekizumab had similar efficacy on the joint manifestations of the disease with better efficacy on the skin. The 52-week data show those results were consistent over time, regardless of concomitant methotrexate use. Physicians can now consider these results when making treatment decisions for their patients with active psoriatic arthritis."

A total of 566 patients with active PsA were enrolled in the SPIRIT-H2H study and were randomized to receive Taltz or Humira at the approved dose for PsA. PsA patients who also met the study criteria for moderate to severe plaque psoriasis received Taltz or Humira at the approved dose for psoriasis. Of the enrolled patients, 87 percent of patients treated with Taltz (N=246) and 84 percent of patients treated with Humira (N=237) participated in the study through 52 weeks.

Taltz performed at least as well as Humira at Week 52 in other secondary endpoints, including:

- ACR50: 50 percent of patients treated with Taltz and 50 percent of patients treated with Humira achieved ACR50 at Week 52;
- ACR70: 35 percent of patients treated with Taltz and 34 percent of patients treated with Humira achieved ACR70 at Week 52;
- PASI 100: 64 percent of patients treated with Taltz and 41 percent of patients treated with Humira achieved PASI 100 at Week 52

"Taltz is the first and only IL-17A antagonist to demonstrate superiority over Humira in a head-to-head trial in psoriatic arthritis. The 52-week results from SPIRIT-H2H show that Taltz maintains consistent efficacy in joint and skin symptoms at one year of treatment," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We believe these data provide further evidence of the efficacy of Taltz as a first-line treatment for patients with active psoriatic arthritis."

The SPIRIT-H2H trial utilized on-label dosing for both Taltz and Humira and allowed inclusion of concomitant conventional DMARDs. More patients achieved simultaneous ACR50 and PASI 100 response with Taltz than Humira, regardless of concomitant methotrexate use.

In SPIRIT-H2H, the safety profile of Taltz was consistent with previously reported results. The most common adverse reactions included infections (42.0 percent for Taltz and 39.2 percent for Humira), injection site reactions (10.6 percent for Taltz and 3.5 percent for Humira), allergic/hypersensitivity reactions (3.9 percent for Taltz and 4.6 percent for Humira), cytopenias (3.2 percent for Taltz and 4.2 percent for Humira) and cerebrocardiovascular events (1.8 percent for Taltz and 2.5 percent for Humira). Most adverse reactions were mild to moderate in severity. Serious adverse events were reported in 4.2 percent for Taltz and 12.4 percent for Humira. Discontinuations due to adverse events were reported in 4.2 percent for Taltz and 7.4 percent for Humira.

Twenty-four-week results from the SPIRIT-H2H study were presented at the European Congress of Rheumatology (EULAR) in June 2019 and published in *Annals of the Rheumatic Diseases* in September 2019.

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved for the treatment of adults with 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 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 PASI 100 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 PASI 100 in Taltz compared to Humira at week 24. 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 Rheumatology
Lilly in Rheumatology aims to create a brighter future for people with debilitating rheumatologic diseases through innovative discoveries and patient-centered solutions.

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 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, 2019.

[2] Ritchlin C, et. al. Psoriatic Arthritis. *New England Journal of Medicine*. 2017;376:957-70.

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