EULAR 2020: Lilly's Taltz® (ixekizumab) Continues to Show Robust and Consistent Efficacy in Psoriatic Arthritis

June 3, 2020

-- Long-term results from SPIRIT-H2H show robust efficacy of Taltz as monotherapy or in combination with methotrexate or additional csDMARDs --

INDIANAPOLIS, June 3, 2020 /PRNewswire/ -- Taltz® (ixekizumab) demonstrated consistent efficacy and long-term potential to help patients with psoriatic arthritis (PsA) in new data to be presented virtually on June 5 at the European Congress of Rheumatology 2020 (EULAR).

Eli Lilly and Company (NYSE: LLY) shared new results today from a subgroup analysis of the Phase 3b/4, 52-week SPIRIT-Head-to-Head (SPIRIT-H2H) study of Taltz versus Humira (adalimumab) in biologic-naïve patients with active psoriatic arthritis (PsA). SPIRIT-H2H was the first superiority study versus Humira in PsA with a primary endpoint of simultaneous achievement of ACR50 (at least 50% improvement in disease activity as defined by the American College of Rheumatology) and PASI 100 (100% improvement in the Psoriasis Area and Severity Index) at Week 24.

In this prespecified analysis, efficacy outcomes through Week 52 were compared between Taltz and Humira in subgroups of patients on monotherapy, concomitant methotrexate (MTX), or concomitant MTX along with an additional conventional synthetic disease-modifying antirheumatic drug (csDMARD), including sulfasalazine, cyclosporine, or leflunomide. Results at 52 weeks showed improvements were seen with Taltz across multiple endpoints, with or without the use of MTX or other csDMARDs.

A higher proportion of patients treated with Taltz achieved Minimal Disease Activity (MDA) compared to Humira in the monotherapy subgroup (49% versus 33%), while response rates were similar between Taltz and Humira in the concomitant MTX subgroup (47% vs 47%) and concomitant csDMARD subgroup (47% vs 44%). MDA is an endpoint that includes fulfilling at least five of seven rheumatology outcome measures and is the treatment target according to multiple professional organizations.

More Taltz patients achieved the primary endpoint of simultaneous achievement of ACR50 and PASI 100 at Week 52 in all three subgroups:

- Monotherapy: Taltz 38%, Humira 19%
- Concomitant MTX: Taltz 39%, Humira 30%
- Concomitant csDMARDS: Taltz 40%, Humira 29%

A greater proportion of patients treated with Taltz versus Humira achieved PASI 100 when used as monotherapy (66% vs 35%), in combination with MTX (63% vs 44%), or in combination with csDMARDs (64% vs 44%) and the proportion of patients achieving ACR50 was comparable between Taltz and Humira, regardless of monotherapy (51% vs 42%), concomitant MTX (48% vs 56%), or concomitant csDMARD use (49% vs 53%).

"In this subgroup analysis of the SPIRIT-H2H study, ixekizumab showed greater improvement than adalimumab across multiple PsA endpoints when taken as monotherapy, and at least comparable efficacy when used in combination with methotrexate or other csDMARDs," said Josef Smolen, M.D., emeritus professor of medicine at the Medical University of Vienna, Austria and lead author of the abstract. "Head-to-head studies provide important insights for physicians when making treatment decisions. The results of this analysis reinforce the efficacy of ixekizumab, even as monotherapy, for patients with PsA who have had an inadequate response to csDMARDs."

The observed safety profile for Taltz in the SPIRIT-H2H study was consistent with that reported for ixekizumab in patients with moderate to severe plaque psoriasis (PsO) and PsA.

Lilly also highlighted notable results from two additional studies. The SPIRIT-P2 study demonstrated sustained improvement in signs and symptoms of PsA, as measured by ACR responses, as well as manifestations of PsA, including enthesitis, dactylitis, and skin outcomes, for up to three years in patients with prior inadequate response or intolerance to one or two tumor necrosis factor inhibitors (TNFi). In the Phase 3 COAST-X study in patients with active non-radiographic axial spondyloarthritis (nr-axSpA), patients treated with Taltz saw improvement in fatigue, spinal pain and stiffness at Week 16. In both studies, the safety profile of Taltz was consistent with previously reported results and no unexpected safety signals were found.

"To date, Taltz has reported positive results from five H2H superiority studies across PsA and PsO, including SPIRIT-H2H, IXORA-S, UNCOVER-2, UNCOVER-3 and IXORA-R, and we're pleased to share additional data from the SPIRIT-H2H subgroup analysis which provides further evidence for the use of Taltz as a first-line monotherapy treatment for patients living with PsA," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "The full breadth of Taltz data being presented at EULAR reinforce the efficacy of Taltz in treating patients with PsA and axSpA."

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation, active psoriatic arthritis, or active ankylosing spondylitis, and for the treatment of patients 6 years of age and older 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 adult 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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. 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
Patients treated with Taltz may be at an increased risk of inflammatory bowel disease. In clinical trials, Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group than the placebo group. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease and if IBD occurs, discontinue Taltz and initiate appropriate medical management.

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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis were consistent with the safety profile in adult patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis and conjunctivitis, influenza, and urticaria in pediatric psoriasis.

Please see full Prescribing Information and Medication Guide for Taltz. See Instructions for Use included with the device.

IX HCP ISI 07MAY2020

About Taltz®
Taltz 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 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 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 the SPIRIT-P2 Study
SPIRIT-P2 is a Phase 3 multicenter, randomized, double-blind, placebo-controlled 24-week study followed by long term evaluation of efficacy and safety of Taltz in patients with prior inadequate response or intolerance to 1 or 2 tumor necrosis factor inhibitors (TNFi). The primary endpoint of the study was percentage of patients achieving ACR20 at Week 24. The 24-week study was followed by an extension period through three years.

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 COAST-X Study
COAST-X is a multicenter, randomized, double-blind, placebo-controlled 52-week study evaluating the efficacy and safety of Taltz for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) in patients with objective signs of inflammation. Patients were required to have an established diagnosis of nr-axSpA and active disease defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Numeric Rating Scale (NRS) score ≥4 and total back pain ≥4 at screening and baseline, and were required to have objective signs of inflammation by presence of sacroiliitis on MRI or presence of elevated CRP.

About the Taltz Program in AxSpA
The COAST-X study is part of a clinical development program that aims to evaluate the efficacy and safety of Taltz across various population subsets of patients with axSpA. The COAST program includes three registration studies each of one year duration: COAST-V in patients with Ankylosing Spondylitis (AS)/radiographic axSpA who are biologic-naive; COAST-W in patients with AS/radiographic axSpA who previously had an inadequate response or were intolerant to tumor necrosis factor (TNF) inhibitors; and COAST-X in biologic-naive nr-axSpA patients with objective signs of inflammation. Patients may enroll into a long-term extension study (COAST-Y) after completion of any of these registration studies to receive Taltz treatment for up to an additional two years.

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 its 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/news. 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 psoriatic arthritis or non-radiographic axial spondyloarthritis 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 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.

[1] Taltz Prescribing Information, 2020.

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

Refer to: Carla Cox; cox_carla@lilly.com; 317-750-3923 (media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (investors)

View original content to download multimedia:http://www.prnewswire.com/news-releases/eular-2020-lillys-taltz-ixekizumab-continues-to-show-robust-and-consistent-efficacy-in-psoriatic-arthritis-301069783.html

SOURCE Eli Lilly and Company