



Lilly Presents Positive Results for Taltz® (ixekizumab) in Pediatric Patients with Moderate to Severe Plaque Psoriasis at the 28th Annual European Academy of Dermatology and Venereology (EADV) Congress

October 12, 2019

Taltz is the first and only IL-17A inhibitor with published clinical trial results in pediatric patients with moderate to severe plaque psoriasis

INDIANAPOLIS, Oct. 12, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that Taltz met co-primary endpoints as well as all major secondary endpoints in a Phase 3 study in pediatric patients with moderate to severe plaque psoriasis, demonstrating that 89 percent of patients treated with Taltz achieved a significant 75 percent improvement from baseline to Week 12 on their Psoriasis Area and Severity Index score (PASI 75) and 81 percent of patients treated with Taltz achieved a static Physician's Global Assessment of clear or almost clear skin (sPGA 0,1). Results of the study are being presented as a late-breaking oral presentation at the European Academy of Dermatology and Venereology Congress (EADV) in Madrid, Spain. Based on these positive results, Lilly plans to submit for U.S. regulatory approval for pediatric patients with moderate to severe plaque psoriasis.

"Results from our study indicate that Taltz may have the potential to clear skin and reduce itch in pediatric patients with moderate to severe plaque psoriasis," said study investigator Kim Papp, MD, PhD, Probitry Medical Research, Inc., Waterloo, Ontario, Canada. "While it is estimated that up to one third of people with psoriasis first develop symptoms during childhood, there are limited medications available for pediatric patients. This study provides encouraging data supporting the potential for Taltz to become another treatment option for this patient population."

The co-primary endpoints of the study were the proportion of patients achieving a significant 75 percent improvement from baseline on their Psoriasis Area and Severity Index score (PASI 75) and a static Physician's Global Assessment of clear or almost clear skin (sPGA 0,1) at Week 12. Key secondary endpoints included the proportion of patients achieving PASI 90, sPGA (0) and PASI 100 at Week 12, and at least a four-point improvement in Itch Numeric Rating Scale (Itch NRS ≥ 4) among patients with baseline Itch NRS ≥ 4 at Week 12, as well as PASI 75 and sPGA 0,1 at Week 4. The proportion of patients achieving 0 or 1 on the Children's Dermatology Life Quality Index (CDLQI, patients 6 to 16 years old) or DLQI (patients ≥ 17 years old) at Week 12 was also evaluated.

"We recognize that psoriasis can have a significant impact on children and adolescents, causing challenging symptoms and affecting their self-esteem and ability to connect to peers," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We're pleased to see positive results for Taltz in pediatric patients. These results build on more than five years of safety and efficacy data in adults and support the potential for Taltz in this new population, pending regulatory approvals."

A total of 201 patients aged 6 to <18 years of age with moderate to severe plaque psoriasis were randomized to receive Taltz (20 mg for <25 kg, 40 mg for 25-50 kg or 80 mg for >50 kg through Week 12, with 40 mg, 80 mg or 160 mg starting doses, respectively) or placebo. At 12 weeks, the proportion of patients achieving the co-primary endpoints was superior to placebo with statistically significant difference ($P < 0.001$), including:

- 89 percent of patients treated with Taltz achieved PASI 75 compared to 25 percent of patients treated with placebo.
- 81 percent of patients treated with Taltz achieved sPGA 0,1 compared to 11 percent of patients treated with placebo.

Taltz also met all major secondary endpoints in the study ($P < 0.001$).

In this trial, the overall safety profile of Taltz was consistent with previously reported results. The Taltz safety profile has been studied across 15 clinical trials in plaque psoriasis and psoriatic arthritis, with 6,989 patients receiving Taltz, with a total exposure of 16,586 patient-years.^{1,2,3}

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of 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 $\leq 0.1\%$), 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 ($\geq 1\%$) 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.⁴ 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.⁴

About Moderate to Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.⁵ 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.^{5,6} The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.⁵ 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.⁵

About the Phase 3 Pediatric Study

This study is a Phase 3, multicenter, randomized, double-blinded, placebo controlled study to evaluate safety, tolerability and efficacy of Taltz in patients from 6 to <18 years of age with moderate to severe plaque psoriasis. The co-primary endpoints of the study were the proportion of patients achieving a 75 percent improvement from baseline on their Psoriasis Area and Severity Index score (PASI 75) and a static Physician's Global Assessment of clear or almost clear skin (sPGA 0,1) at Week 12. Key secondary endpoints included the proportion of patients achieving PASI 90, sPGA 0 and PASI 100 at Week 12, and at least a four-point improvement in Itch numeric rating scale (Itch NRS ≥ 4) among patients with baseline Itch NRS ≥ 4 at Week 12, as well as PASI 75 and sPGA 0,1 at Week 4. The proportion of patients achieving 0 or 1 on the Children's Dermatology Life Quality Index (CDLQI, patients 6 to 16 years old) or DLQI (patients ≥ 17 years old) at Week 12 was also evaluated.

About Lilly in Dermatology

By following the science through uncharted territory, we continue Lilly's legacy of delivering innovative medicines that address unmet needs and have significant impacts on people's lives around the world. Skin-related diseases are more than skin deep. We understand the devastating impact this can have on people's lives. At Lilly, we are relentlessly pursuing a robust dermatology pipeline to provide innovative, patient-centered solutions so patients with skin-related diseases can aspire to live life without limitations.

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 potential treatment for pediatric 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 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 Data on file. Lilly USA, LLC. TAL20171211A.

² Data on file. Lilly USA, LLC. DOF-IX-US-0019.

³ Mease P, Roussou E, Burmester GR, et al. Safety of ixekizumab in patients with psoriatic arthritis: results from a pooled analysis of three clinical trials. *Arth Care Res*. 2018 (Epub). doi:10.1002/acr.23738.


⁴ Taltz Prescribing Information, 2019.

⁵ Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed September, 2019.

⁶ Skin conditions by the numbers. American Academy of Dermatology website. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed September, 2019.

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The Lilly logo is rendered in a vibrant red, cursive script. The letters are fluid and interconnected, with a classic, elegant feel. The 'L' is particularly large and prominent, leading into the 'i', 'l', 'l', 'e', and 'y' which follow in a similar flowing style. The overall appearance is that of a handwritten signature or a stylized brand mark.

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