



Lilly's Taltz® (ixekizumab) Receives U.S. FDA Approval for the Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis

March 30, 2020

-- Taltz is the first and only IL-17A antagonist approved to treat this population --

INDIANAPOLIS, March 30, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for Taltz® (ixekizumab) injection, 80 mg/mL for the treatment of pediatric patients (ages 6 to under 18) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Psoriasis affects nearly 8 million people in the U.S.¹ Many people living with psoriasis develop symptoms during childhood.²

"As I have often seen in my clinic, psoriasis is particularly challenging for children and adolescents, resulting in itchy and painful symptoms that can feel especially embarrassing for pediatric patients during a crucial developmental period in their young lives," said Jennifer Cather, M.D., Modern Research Associates, Dallas, Texas. "In the Phase 3 pediatric study, half of patients treated with Taltz achieved completely clear skin after only 12 weeks of treatment. These results and the subsequent FDA approval make a strong case for Taltz as an effective treatment option for doctors to consider for pediatric patients with moderate to severe plaque psoriasis."

Taltz should not be used in patients with a previous serious hypersensitivity, such as anaphylaxis, to ixekizumab or to any of the excipients. Taltz may increase the risk of infection. Other warnings and precautions for Taltz include pre-treatment evaluation for tuberculosis, hypersensitivity, inflammatory bowel disease, and immunizations. See Important Safety Information below.

"At Lilly, we are working to unite our compassion for individuals with our enthusiasm for scientific discovery in an effort to provide medicines that help make life better for people," said Patrik Jonsson, senior vice president and president of Lilly Bio-Medicines. "We have over five years of data demonstrating that Taltz is a safe and effective treatment option for psoriasis in adults, and with this approval, we're pleased to now be able to offer Taltz to more people living with this challenging condition."

The safety, tolerability and efficacy of Taltz in patients ages 6 to under 18 was demonstrated in a randomized, double-blind, placebo-controlled Phase 3 study that included 171 patients 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.

Patients 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 ($P < 0.001$):

- 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 ($P < 0.001$), which 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.

Overall, the safety profile observed in pediatric patients with plaque psoriasis treated with Taltz every four weeks is consistent with the safety profile in adult patients with plaque psoriasis, with the exception of the frequencies of conjunctivitis (3%), influenza (2%) and urticaria (2%). In this clinical trial, Crohn's disease occurred at a greater frequency in the Taltz group (0.9%) than the placebo group (0%) during the 12-week, placebo-controlled period. Crohn's disease occurred in a total of four Taltz-treated subjects (2.0%) in the clinical trial. The Taltz safety profile has been studied across 13 clinical trials in adult subjects with plaque psoriasis, with over 5,000 patients receiving Taltz, with a total exposure of over 17,000 patient-years.

"Due to limited pediatric psoriasis treatment options available, treating children and adolescents with moderate to severe plaque psoriasis can be challenging," said Stacie Bell, chief scientific and medical officer, National Psoriasis Foundation. "Having more FDA approved pediatric psoriasis treatment options available is a positive step forward in helping relieve the burden of psoriasis for pediatric patients, their families and the health care providers that treat these young patients."

Taltz was first approved by the FDA in March 2016 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. The FDA also approved Taltz for the treatment of adults with active psoriatic arthritis in December 2017 and for the treatment of adults with active ankylosing spondylitis in August 2019.

Lilly will work with insurers, health systems and providers to ensure patients are able to access this treatment. Patients, physicians, pharmacists or other healthcare professionals with questions about Taltz should contact The Lilly Answers Center at **1-800-LillyRx (1-800-545-5979)** or visit www.lilly.com.

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of pediatric patients ages 6 to under 18 with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In addition, 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 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 and ankylosing spondylitis, 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 $\leq 0.1\%$), 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

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 ($\geq 1\%$) 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 and ankylosing spondylitis 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.

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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.³ 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.³

About the Phase 3 Pediatric Study

The FDA approval of Taltz in pediatric patients with moderate to severe plaque psoriasis was based on a Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate safety, tolerability and efficacy of Taltz in patients from 6 to under 18 years of age. 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.

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/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 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 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 Statistics. National Psoriasis Foundation website. <https://www.psoriasis.org/content/statistics>. Accessed March, 2020.

² Menter A, Cordoro K, Davis D et al. Joint American Academy of Dermatology National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82:161-201.

³ Taltz Prescribing Information, 2020.

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a prominent 'L' at the beginning and a long, sweeping tail on the 'y'.

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