AAD 2018: Treatment with Lilly's Taltz® (ixekizumab) Resulted in Improvement in Impact of Genital Psoriasis on Sexual Activity

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- Reductions in the impact of genital psoriasis on sexual activity seen as early as one week -

INDIANAPOLIS, Feb. 19, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that patients with moderate-to-severe genital psoriasis treated with Taltz® (ixekizumab) reported a greater decrease in the impact of their condition on sexual activity compared to placebo after 12 weeks of treatment. Results from the Phase 3b trial will be presented in an oral presentation today at the annual meeting of the American Academy of Dermatology, taking place February 16-20, in San Diego, Calif.

"Over the course of their disease, up to 63 percent of psoriasis patients experience genital psoriasis, which can be difficult to treat and can have a significant impact on their sexual health," said Dr. Lotus Mallbris, vice president, immunology platform team leader, product development. "We look forward to fostering a discussion at AAD about the need for healthcare providers to address this important issue affecting people living with psoriasis."

In the study, 149 patients with moderate-to-severe genital psoriasis were randomized to receive Taltz (80 mg every two weeks, following a 160-mg starting dose) or placebo. The impact of genital psoriasis on sexual activity was measured at 12 weeks by pre-specified patient-reported outcomes, including the Genital Psoriasis Sexual Impact Scale (GPSIS), which is composed of the Sexual Activity Avoidance (Avoidance) and Impact of Sexual Activity on Genital Psoriasis Symptoms (Impact) subscales. Patient-reported outcomes were also measured by the Sexual Frequency Questionnaire (SFQ) item 2, evaluating the impact of genital psoriasis on the frequency of sexual activity, and the Dermatology Life Quality Index (DLQI) item 9, evaluating the impact of skin symptoms on sexual difficulties.

At 12 weeks, patients reported the following outcomes:

- **DLQI Item 9 0/1:** 92.0 percent of patients treated with Taltz compared to 56.8 percent of patients treated with placebo ($p<0.001$) reported no (0) or little (1) sexual difficulties caused by skin symptoms.
- **SFQ Item 2 0/1:** 78.4 percent of patients treated with Taltz compared to 21.4 percent of patients treated with placebo ($p<0.001$) reported the frequency of sexual activity was either never (0) or rarely (1) limited by genital psoriasis.
- **GPSIS-Avoidance 1/2:** 76.7 percent of patients treated with Taltz compared to 25.7 percent of patients treated with placebo ($p<0.001$) reported never (1) or rarely (2) avoiding sexual activity due to genital psoriasis.
- **GPSIS-Impact 1/2:** 85.7 percent of patients treated with Taltz compared to 52.9 percent of patients treated with placebo ($p=0.062$) reported worsening of genital psoriasis symptoms during or after sexual activity was very low/none at all (1) or low (2).

Taltz was superior to placebo as early as week one on the limitations on frequency of sexual activity due to genital psoriasis ($p<0.05$), week two for the sexual difficulties caused by skin symptoms ($p<0.001$).

"Genital psoriasis can be an uncomfortable and burdensome condition for patients to manage," said Jennifer Clay Cather, M.D., Modern Research Associates, Dallas, Texas. "This condition can have a significant impact on patients' sexual health and experience."

The most common (≥4 percent) adverse events observed in patients treated with Taltz in this study were upper respiratory tract infections, injection-site reactions, headache, oropharyngeal pain and pruritus. The safety outcomes were consistent with the overall safety profile of Taltz.

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

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. 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.

About Moderate-to-Severe Plaque Psoriasis
Psoriasis is a chronic, immune disease that affects the skin.[1] 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.[1,2] Psoriasis can occur on any part of the body, including the genital area.[1] Up to 63 percent of psoriasis patients experience genital psoriasis over the course of their disease.[3] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[1] Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease.[1]

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to 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.

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Taltz (ixekizumab) in patients with moderate-to-severe plaque psoriasis, who also have psoriasis in the genital area, and reflects Lilly's current belief. Lilly considers patients with genital psoriasis as a sub-population of patients with moderate-to-severe plaque psoriasis. 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 undertakes no duty to update forward-looking statements to reflect events after the date of this release.

[1] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed February 19, 2018.
[2] Skin conditions by the numbers. American Academy of Dermatology website. https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed February 19, 2018.
[3] Ryan C, et al. J Am Acad Dermatol. 2015;72:978-983

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