



February 28, 2017

Lilly to Present New Data for Taltz® (ixekizumab) in Psoriasis and Psoriatic Arthritis at the American Academy of Dermatology (AAD) Annual Meeting

INDIANAPOLIS, Feb. 28, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will highlight new Phase 3 data evaluating Taltz® (ixekizumab) for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis at the 75th annual meeting of the American Academy of Dermatology (AAD), which will take place March 3-7, 2017, in Orlando, Fla.

Lilly will present 14 abstracts, including one oral late-breaker presentation highlighting head-to-head data on the efficacy and safety of Taltz compared to Stelara®* (ustekinumab) for the treatment of moderate-to-severe plaque psoriasis at 24 weeks.

"As the world's largest dermatology meeting, the American Academy of Dermatology annual meeting is an opportunity to highlight new information and data to experts in the dermatologic disease field," said Dr. Lotus Mallbris, global brand development leader, Taltz, Eli Lilly and Company. "Nearly one year after the approval of Taltz in the U.S. and Europe, we are proud to bring new data further demonstrating the efficacy and safety of Taltz to the American Academy of Dermatology annual meeting."

Studies, as well as the times and locations of the data sessions, are highlighted below.

Oral Late-Breaker Presentation

Saturday, March 4

- | Abstract #5174: 9 a.m. - 11 a.m. ET
 - | Efficacy and Safety of Ixekizumab Compared to Ustekinumab after 24 Weeks of Treatment in Patients with Moderate-to-Severe Plaque Psoriasis: Results from IXORA-S, a Randomized Head-to-Head Trial
 - | Presenter: Kristian Reich, M.D., Ph.D., Georg-August-University Göttingen and Dermatologikum Hamburg, Hamburg, Germany
 - | Location: F056 - Late-breaking Research: Clinical Trials

Poster Presentations

Sunday, March 5

- | Abstract #4622: 8:15 a.m. - 8:20 a.m. ET
 - | The Effects of Age, Gender, Weight, Age at Onset, Psoriasis Severity, Nail Involvement and Presence of Psoriatic Arthritis at Baseline on the Efficacy of Ixekizumab in Patients with Moderate-to-Severe Psoriasis
 - | Presenter: Orin Goldblum, M.D., Eli Lilly & Company, Indianapolis, IN
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4663: 8:20 a.m. - 8:25 a.m. ET
 - | Incidence of Inflammatory Bowel Disease Among Ixekizumab-treated Patients with Moderate-to-Severe Plaque Psoriasis and Psoriatic Arthritis: Data from Eight Clinical Trials
 - | Presenter: Dana S. Hardin, M.D., St. Vincent Indianapolis Hospital & Heart Center, Indianapolis, IN
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4376: 9:15 a.m. - 9:20 a.m. ET
 - | Efficacy and Safety of Ixekizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis: Results Through 108 Weeks of a Randomized, Phase 3 Clinical Trial (UNCOVER-3)
 - | Presenter: Andrew Blauvelt, M.D., M.B.A., Oregon Medical Research Center, Portland, OR
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4551: 9:30 a.m. - 9:35 a.m. ET
 - | Clearing of Psoriasis within Different Body Regions Following 12 Weeks of Treatment with Ixekizumab
 - | Presenter: Andrew Blauvelt, M.D., M.B.A., Oregon Medical Research Center, Portland, OR
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4662: 11:25 a.m. - 11:30 a.m. ET

- | Ixekizumab Treatment Shows a Neutral Impact on the Glucose and Lipid Profile of Patients with Moderate-to-Severe Psoriasis: Results from UNCOVER-1, -2, and -3
 - | Presenter: Jashin J. Wu, M.D., Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4629: 12:50 p.m. - 12:55 p.m. ET
 - | Ixekizumab Efficacy in Patients with Moderate-to-Severe Plaque Psoriasis and Co-Morbid Psoriatic Arthritis: Four Year Results from a Phase 2 Study
 - | Presenter: Mark Lebwohl, M.D., Mount Sinai Hospital, New York City, NY
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4664: 2:20 p.m. - 2:25 p.m. ET
 - | Patients' Perspectives on the Impact of Moderate-to-Severe Genital Psoriasis
 - | Presenter: Jennifer Clay Cather, M.D., Baylor University Medical Center, Dallas, TX
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4550: 2:35 p.m. - 2:40 p.m. ET
 - | Ixekizumab Treatment Shows No Evidence for Reactivation of Previous or Latent Tuberculosis Infection in Subjects with Psoriasis: An Integrated Analysis of Seven Clinical Trials
 - | Presenter: Ricardo Romiti, M.D., Dermatologia e Preceptoria pelo Hospital das Clinicas da Universidade de Sao Paulo, Sao Paulo, BR
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4548: 2:55 p.m. - 3:00 p.m. ET
 - | The Burden of Moderate-to-Severe Genital Psoriasis: Patients' Perspectives on Symptoms
 - | Presenter: Caitriona Ryan, M.D., Texas A&M Health Science Center, Dallas, TX
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4530: 3:00 p.m. - 3:05 p.m. ET
 - | The Effect of Ixekizumab on Scalp and Nail Psoriasis and Health Outcome Measures Over Four Years of Open-Label Treatment in a Phase 2 Study in Chronic Plaque Psoriasis
 - | Presenter: Russel Burge, Ph.D., Eli Lilly & Company, Indianapolis, IN
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #4532: 3:20 p.m. - 3:25 p.m. ET
 - | Ixekizumab and Pregnancy Outcome
 - | Presenter: Lars Iversen, M.D., Department of Clinical Medicine, Aarhus University, Aarhus, Denmark
 - | Location: Psoriasis & Other Papulosquamous Disorders Section
- | Abstract #5105: 4:05 p.m. - 4:10 p.m. ET
 - | Treatment with Ixekizumab Does Not Interfere with the Efficacy of Tetanus and Pneumococcal Vaccines in Healthy Subjects
 - | Presenter: Talia Muram, IU Health Pathology Laboratory, Indianapolis, IN
 - | Location: E-Poster Presentation Center #2
- | Abstract #4750: 4:20 p.m. - 4:25 p.m. ET
 - | Absolute and Relative Psoriasis Area and Severity Indices for Comparison of the Efficacy of Ixekizumab versus Etanercept and Placebo in Patients with Moderate-to-Severe Plaque Psoriasis
 - | Presenter: Martin Dossenbach, M.D., Senior Medical Fellow, Medical Leader Dermatology, Eli Lilly & Company, Vienna, Austria
 - | Location: Psoriasis & Other Papulosquamous Disorders Section

Indications and Usage

Taltz[®] (ixekizumab) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

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. The Taltz group had a higher rate of infections than the placebo group (27% vs. 23%). 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. Patients receiving Taltz should be monitored closely for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including anaphylaxis, angioedema and urticaria, have been reported 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. 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. Live vaccines should not be given 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.

Please see accompanying [Prescribing Information](#) and [Medication Guide](#). Please see [Instructions for Use](#) included with the device.

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About Taltz[®] (ixekizumab)

Taltz[®] (ixekizumab) is an IgG4 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 and is associated with other serious health conditions, such as diabetes and heart disease.¹ The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.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 newsroom.lilly.com/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) as a treatment for 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 Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed February 23, 2017.

² Psoriasis. American Academy of Dermatology website. <https://www.aad.org/media-resources/stats-and->

[facts/conditions/psoriasis](#). Accessed February 23, 2017.

Refer to: Jen Dial; dial_jennifer_kay@lilly.com; 317-220-1172 (Lilly Bio-Medicines)

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