



Lilly to Present Data Demonstrating Continued Scientific Advancements in Broad Dermatology Portfolio at AAD Annual Meeting

March 1, 2019

- Over 25 abstracts for medicines in Lilly's dermatology portfolio, including Taltz® (ixekizumab), highlight new findings for the treatment of patients with moderate-to-severe plaque psoriasis, including genital psoriasis and active psoriatic arthritis -

INDIANAPOLIS, March 1, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that it will present data for Taltz® (ixekizumab) and mirikizumab at the American Academy of Dermatology (AAD) annual meeting taking place March 1-5, 2019 in Washington, DC.

The data include 20 abstracts for Taltz, featuring ten oral presentations and notable results from the UNCOVER-3 and IXORA-Q trials. Lilly will present long-term efficacy (4 years) and safety (exposures up to 5 years) data on Taltz in patients with moderate-to-severe plaque psoriasis, as well as data on onset of action, genital psoriasis and sustained efficacy and safety. These studies, which include seven presentations demonstrating real world evidence in addition to results from clinical trials, reflect the breadth of data collected on Taltz in moderate-to-severe plaque psoriasis and active psoriatic arthritis.

Additionally, Lilly will present data regarding short- and long-term efficacy, safety and patient-rated outcomes for its investigational product, mirikizumab, in four abstracts from a Phase 2 study evaluating patients with moderate-to-severe plaque psoriasis. Lilly will also present two abstracts highlighting real world data on the healthcare resource utilization and costs associated with atopic dermatitis and a global investigator's assessment scale to help define a clinically meaningful response in the treatment of alopecia areata.

"At Lilly, we recognize the impact autoimmune diseases such as moderate-to-severe plaque psoriasis and active psoriatic arthritis have on patients' lives, and we're dedicated to leveraging our deep scientific expertise to find treatment options that best meet individual needs," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "By exploring treatments that inhibit IL-17A, IL-23 and JAK cytokines, Lilly is working to build a dermatology portfolio that will provide flexibility for dermatologists and their patients."

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

Taltz Data

Oral Presentations (All times EST)

Real World Evidence

Friday, March 1

- Abstract 9884: 8:55 - 9:00 AM, ePoster Presentation Center 1
 - Real World Use of Ixekizumab is Associated with Reductions in Concomitant Medications Among Biologic-Experienced or Biologic-Naïve Patients with Psoriasis
 - Presenter: Orin Goldblum
- Abstract 10157: 12:15 - 12:20 PM, ePoster Presentation Center 1
 - Comparison of Treatment Patterns and Healthcare Costs between Ixekizumab and Adalimumab Users among Psoriasis Patients
 - Presenter: Andrew Blauvelt
- Abstract 8211: 12:40 - 12:45 PM, ePoster Presentation Center 1
 - Disease Severity and Quality of Life among Ixekizumab-Treated Psoriasis Patients in the Real-World Setting: Results from a Single US Dermatology Referral Practice
 - Presenter: Craig Leonardi
- Abstract 9832: 12:40 - 12:45 PM, ePoster Presentation Center 2
 - Federal Adverse Event Reporting System (FAERS) Post-Marketing Reports of Injection Site Reactions with Biologics Approved to Treat Moderate-to-Severe Psoriasis
 - Presenter: Orin Goldblum

Clinical Data

Friday, March 1

- Abstract 9997: 11:50 AM - 11:55 AM, ePoster Presentation Center 1
 - Understanding Differences Between Measures of Disease Severity Used in Psoriasis Clinical Trials, How They are Evaluated and Implications for Interpretation of Clinical Trial Data
 - Presenter: Craig Leonardi

Saturday, March 2

- Abstract 8051: 12:05 - 12:10 PM, ePoster Presentation Center 1
 - Indirect Comparison of Ixekizumab Versus Tildrakizumab for Up to 12 Weeks of Treatment in Patients with Moderate-to-Severe Psoriasis
 - Presenter: Saxon Smith
- Abstract 10012: 12:50 PM - 12:55 PM, ePoster Presentation Center 1
 - Rapid Response of Biologic Treatments of Moderate-to-Severe Plaque Psoriasis: A Comprehensive Investigation Using Bayesian and Frequentist Network Meta-Analyses
 - Presenter: Kyoungah See

Sunday, March 3

- Abstract 10011: 1:25 - 1:30 PM, ePoster Presentation Center 1
 - Sustained High Level of Efficacy and Favorable Safety of Ixekizumab in Psoriasis: 4 Years of Follow-Up from UNCOVER-3
 - Presenter: Mark Lebwohl
- Abstract 10070: 2:10 - 2:15 PM, ePoster Presentation Center 1
 - Value of PASI 90 Versus Merit-Based Incentive Payment System (MIPS) Efficacy Measures
 - Presenter: Paulo Reis
- Abstract 10116: 2:25 - 2:30 PM, ePoster Presentation Center 1
 - Patient Perspectives on Injection Site Reactions in 2 Phase 3 Trials of Ixekizumab Versus Etanercept and Placebo in Psoriasis
 - Presenter: Talia Muram

Posters

Real World Evidence

- Abstract 8153:
 - Disease Response Outcomes Among Ixekizumab Patients: Findings from the Corrona Registry
 - Presenter: Mona Shahriari
- Abstract 8155:
 - Patient-Reported Outcomes and Response to Treatment for Patients Initiating Ixekizumab: Findings from the Corrona Registry
 - Presenter: Mona Shahriari
- Abstract 10123:
 - Comparison of Treatment Patterns and Healthcare Costs between Ixekizumab and Secukinumab Users among Psoriasis Patients
 - Presenter: Andrew Blauvelt

Clinical Data

- Abstract 8334:
 - Persistent Clinical Improvement in Genital Psoriasis through One Year of Treatment with Ixekizumab: Results of a Randomized, Placebo-Controlled Phase 3 Clinical Trial in Patients with Moderate-to-Severe Genital Psoriasis (IXORA-Q)
 - Presenter: Lyn Guenther
- Abstract 9775:
 - Indirect Comparison of Ixekizumab Versus Risankizumab For Up To 12 Weeks of Treatment in Patients with Moderate-to-Severe Psoriasis
 - Presenter: Alice Gottlieb
- Abstract 9840:
 - Ixekizumab Treatment Results in More Rapid Clinical Improvements in Patients with Moderate-to-Severe Psoriasis Compared to Ustekinumab: Results from the IXORA-S Trial
 - Presenter: Andreas Pinter
- Abstract 10105:
 - Rapid and Sustained Improvements in Cutaneous and Musculoskeletal Signs and Symptoms with 108 Weeks

Treatment of Ixekizumab in Psoriatic Arthritis in Biologic- Naïve and TNF-Inadequate Responder Patients

- Presenter: Alice Gottlieb
- Abstract 10117:
 - Rapid Clinical Response Predicts Consistent Long-Term Response in Patients with Moderate-to-Severe Psoriasis: Ixekizumab vs. Ustekinumab
 - Presenter: Matthias Augustin
- Abstract 10158:
 - Long-Term Safety of Ixekizumab with Over 18,000 Patient Years of Exposure: Analysis from 12 Moderate-to-Severe Plaque Psoriasis Studies and 3 Psoriatic Arthritis Studies
 - Presenter: Alice Gottlieb
- Abstract 10236:
 - Long-Term Benefit of Ixekizumab Treatment in Japanese Patients in Terms of Symptoms and Quality of Life
 - Presenter: Russel Burge

Mirikizumab Data

Posters

- Abstract 10181:
 - Maintenance of Response in Patients with Moderate-To-Severe Plaque Psoriasis Treated With Mirikizumab and Retreatment Response After Loss of Efficacy
 - Presenter: Kristian Reich
- Abstract 10212:
 - Impact of Mirikizumab Maintenance Dosing on Patient-reported Signs and Symptoms of Psoriasis: A Phase 2 Study Analysis in Patients With <PASI 90 Response at Week 16
 - Presenter: Catherine Maari
- Abstract 10222:
 - Impact of Mirikizumab Treatment on Psoriasis Disease Activity at Week 16 in Patients Based Upon Prior Treatment with Biologic Therapy
 - Presenter: Atsuyuki Igarashi
- Abstract 10230:
 - Impact of Mirikizumab Maintenance Dosing on Patients Who Had <PASI 90 Response at Week 16: A Phase 2 Study Analysis Using the DLQI
 - Presenter: Robert Bissonnette

Additional Data

Posters

Real World Evidence

- Abstract 8610:
 - Resource Utilization and Costs Over 3 Years Following Atopic Dermatitis Claims in the United States
 - Presenter: Jonathan Silverberg

Clinical Data

- Abstract 8606:
 - The Alopecia Areata Investigator's Global Assessment (AA-IGA™) Scale: A Measure for Evaluating Clinically Meaningful Success in Clinical Trials
 - Presenter: Kathleen Wyrwich

INDICATIONS AND USAGE FOR TALTZ (ixekizumab) injection

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 $\leq 0.1\%$), 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

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.ⁱ 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 Mirikizumab

Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the P19 subunit of interleukin 23. Mirikizumab is being studied for the treatment of immune diseases, including psoriasis, ulcerative colitis and Crohn's disease.

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 healthcare 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 www.lilly.com and www.lilly.com/newsroom/social-channels. 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 moderate-to-severe plaque psoriasis and active psoriatic arthritis; and mirikizumab as a potential treatment for moderate-to-severe plaque psoriasis, and reflects Lilly's current belief. 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.

ⁱ Taltz Prescribing Information, 2018.

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Lilly

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