



October 30, 2017

Lilly to Present New Data on Immunology Portfolio at ACR/ARHP Annual Meeting

Highlights include new data for baricitinib in rheumatoid arthritis and Taltz in plaque psoriasis and psoriatic arthritis

INDIANAPOLIS, Oct. 30, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that it will present new data for baricitinib and Taltz[®] (ixekizumab) at the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) annual meeting taking place Nov. 3-8, 2017, in San Diego, Calif.

Lilly will feature new data for baricitinib in 17 abstracts, including six oral presentations on rheumatoid arthritis (RA) (Lilly and Incyte Corporation are partners on the development of baricitinib). Highlights include a new post-hoc analysis from RA-BEAM, a pivotal Phase 3 study, disclosing outcomes of patient-reported levels of pain control, as well as new findings from two safety analyses evaluating cardiovascular safety and long-term use of baricitinib in RA, respectively.

Additionally, Lilly will present eight abstracts featuring new data for Taltz, including two oral presentations. Highlights from the oral presentations include interim results from the extension period of the SPIRIT-P2 study evaluating the safety and efficacy of Taltz for the treatment of active psoriatic arthritis (PsA), in addition to a new analysis from the IXORA-S study comparing Taltz to Stelara^{®**} (ustekinumab) for the treatment of nail lesions in patients with moderate-to-severe plaque psoriasis.

An additional eight abstracts will detail results from a selection of studies evaluating the impact of immune-mediated diseases.

"At Lilly, patients are at the heart of what we do every day," said Lotus Mallbris, M.D., vice president, immunology platform team leader, Lilly Bio-Medicines. "We are proud to present new data at ACR/ARHP from our continued research with the goal to help provide more treatment options for people living with autoimmune diseases."

Highlighted presentations and posters include:

Baricitinib Data

Oral Presentations (All times PST)

Sunday, Nov. 5

- | Abstract 855: 2:30-4:00 p.m.
 - | Rapid and Sustained Pain Improvement in Rheumatoid Arthritis Patients Treated with Baricitinib Compared to Adalimumab or Placebo
 - | Presenter: Peter Taylor, M.A., Ph.D., F.R.C.P., F.R.C.P.E., University of Oxford, Oxford, United Kingdom

Monday, Nov. 6

- | Abstract 1821: 2:30-4:00 p.m.
 - | Dose Reduction of Baricitinib in Patients with Rheumatoid Arthritis Achieving Sustained Disease Control: Results of a Prospective Study
 - | Presenter: Tsutomu Takeuchi, M.D., Ph.D., Keio University School of Medicine, Tokyo, Japan
- | Abstract 1824: 2:30-4:00 p.m.
 - | Evaluation of Pneumococcal and Tetanus Vaccine Responses in Patients with Rheumatoid Arthritis Receiving Baricitinib: Results from a Long-Term Extension Trial Substudy
 - | Presenter: Kevin Winthrop, M.D., M.P.H., Oregon Health and Science University, Portland, OR, United States

Tuesday, Nov. 7

- | Abstract 2787: 2:30-4:00 p.m.
 - | Tuberculosis, Potential Opportunistic Infections, and Other Infections of Interest in Patients with Moderate to Severe Rheumatoid Arthritis in the Baricitinib Program
 - | Presenter: Kevin Winthrop, M.D., M.P.H., Oregon Health and Science University, Portland, OR, United States
- | Abstract 2866: 4:30-6:00 p.m.
 - | Microarray Pathway Analysis Comparing Baricitinib and Adalimumab in Moderate to Severe Rheumatoid Arthritis Patients, from a Phase 3 Study
 - | Presenter: Paul Emery, M.D., Leeds MSK Biomed/Chapel Allerton Hospital, Leeds, United Kingdom
- | Abstract 2870: 4:30-6:00 p.m.
 - | Ex Vivo Comparison of Baricitinib, Upadacitinib, Filgotinib and Tofacitinib for Cytokine Signaling in Human Leukocyte Subpopulations
 - | Presenter: Iain McInnes, M.D., Ph.D., University of Glasgow, Glasgow, United Kingdom

Poster Presentations (All times PST)

Sunday, Nov. 5

- | Abstract 409: 9:00-11:00 a.m.
 - | An Evaluation of Absolute Neutrophil Count as a Biomarker of Inflammatory and Clinical Disease Activity in Baricitinib-Treated Patients
 - | Presenter: Iain McInnes, M.D., Ph.D., University of Glasgow, Glasgow, United Kingdom
- | Abstract 415: 9:00-11:00 a.m.
 - | Baricitinib Reduces GlycA Levels in Phase 2 and Phase 3 Clinical Trials in Patients with Moderate-to-Severe Rheumatoid Arthritis
 - | Presenter: Joel Kremer, M.D., F.A.C.P., The Center for Rheumatology, Albany, NY, United States
- | Abstract 418: 9:00-11:00 a.m.
 - | Exploratory Analysis to Identify Factors Associated with Risk of Structural Progression, Defined as Change from Baseline
 - | Presenter: Désirée van der Heijde, M.D., Ph.D., Leiden University Medical Center, Leiden, The Netherlands
- | Abstract 499: 9:00-11:00 a.m.
 - | Assessment of Early Improvement in Pain and Other ACR components as Predictors for Achieving Low Disease Activity or Remission in Three Phase 3 Trials of Rheumatoid Arthritis Patients Treated with Baricitinib
 - | Presenter: Michael Weinblatt, M.D., Brigham and Women's Hospital, Boston, MA, United States
- | Abstract 502: 9:00-11:00 a.m.
 - | Reduction in Disease Activity in Patients with Rheumatoid Arthritis and an Inadequate Response to Methotrexate: Baricitinib Compared to Adalimumab and Placebo
 - | Presenter: Peter Nash, M.D., University of Queensland, Queensland, Australia
- | Abstract 508: 9:00-11:00 a.m.
 - | Improved Patient-Reported Outcomes in Patients with Rheumatoid Arthritis Who Failed Adalimumab or Placebo Treatment and Were Rescued with Baricitinib
 - | Presenter: Bruno Fautrel, M.D., Ph.D., Pitié Salpêtrière University, Paris, France
- | Abstract 511: 9:00-11:00 a.m.
 - | Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 5.5 Years: An Updated Integrated Safety Analysis
 - | Presenter: Mark Genovese, M.D., Stanford University Medical Center, Palo Alto, CA, United States
- | Abstract 512: 9:00-11:00 a.m.
 - | Efficacy Response to Baricitinib Based on Baseline Characteristics in Patients Who Are Inadequate Responders to Conventional DMARD
 - | Presenter: Maxime Dougados, M.D., Rene Descartes University, Cochin Hospital, Paris, France
- | Abstract 513: 9:00-11:00 a.m.
 - | Time to Achieve Moderate/Low Disease Activity and Remission in Rheumatoid Arthritis Patients on Baricitinib Compared to Adalimumab, Methotrexate and Placebo
 - | Presenter: Edward Keystone, M.D., The University of Toronto, Toronto, ON, Canada

Tuesday, Nov. 7

- | Abstract 2219: 9:00-11:00 a.m.
 - | Remaining Pain in DMARD-naïve Rheumatoid Arthritis Patients Treated with Baricitinib and Methotrexate
 - | Presenter: Yvonne Lee, M.D., Brigham and Women's Hospital, Boston, MA, United States
- | Abstract 2352: 9:00-11:00 a.m.
 - | Cardiovascular Safety during Treatment with Baricitinib in Rheumatoid Arthritis
 - | Presenter: Michael Weinblatt, M.D., Brigham and Women's Hospital, Boston, MA, United States

Oral Presentations (All Times PST)

Monday, Nov. 6

- | Abstract 1827: 2:30-4:00 p.m.
 - | Comparison of Ixekizumab and Ustekinumab Efficacy in the Treatment of Nail Lesions of Patients with Moderate-to-Severe Plaque Psoriasis: 24-Week Data from a Phase 3 Trial
 - | Presenter: David Sandoval, Eli Lilly and Company, Indianapolis, IN, United States

Wednesday, Nov. 8

- | Abstract 2969: 11:00 a.m.-12:30 p.m.
 - | Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to TNF inhibitors: 52-week Results from a Phase 3 Study
 - | Presenter: Mark Genovese, M.D., Stanford University Medical Center, Palo Alto, CA, United States

Poster Presentations (All Times PST)

Sunday, Nov. 5

- | Abstract 597: 9:00-11:00 a.m.
 - | Ixekizumab Improves Patient-Reported Outcomes Through 52 Weeks in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to Tumor Necrosis Factor-Inhibitors
 - | Presenter: Arthur Kavanaugh, M.D., University of California, San Diego, La Jolla, CA, United States
- | Abstract 605: 9:00-11:00 a.m.
 - | Ixekizumab Exhibits a Favorable Safety Profile During 24 Weeks of Treatment in Subjects with Active Psoriatic Arthritis: Integrated Safety Analysis of Two Randomized, Placebo Controlled, Phase 3 Clinical Trials
 - | Presenter: Philip J. Mease, M.D., Swedish Medical Center and University of Washington, Seattle, WA, United States
- | Abstract 624: 9:00-11:00 a.m.
 - | Ixekizumab Provides Sustained Improvement in Signs and Symptoms in Patients with Active Psoriatic Arthritis: Two Year Results from a Phase 3 Trial
 - | Presenter: Philip S. Helliwell, St. Luke's Hospital and University of Leeds, Bradford, United Kingdom
- | Abstract 625: 9:00-11:00 a.m.
 - | Rapid Onset of Efficacy in Patients with Active Psoriatic Arthritis Treated with Ixekizumab: A Pooled Analysis of Data from Two Phase 3 Clinical Trials
 - | Presenter: Atul A. Deodhar, M.D., M.R.C.P., Oregon Health and Science University, Portland, OR, United States
- | Abstract 626: 9:00-11:00 a.m.
 - | Radiographic Progression of Structural Joint Damage in Patients with Active Psoriatic Arthritis Treated with Ixekizumab over 52 Weeks
 - | Presenter: Désirée van der Heijde, M.D., Ph.D., Leiden University Medical Center, Leiden, The Netherlands
- | Abstract 628: 9:00-11:00 a.m.
 - | Integrated Efficacy Results from Two Phase 3 Trials of Ixekizumab for the Treatment of Psoriatic Arthritis
 - | Presenter: Bernard Combe, M.D., Ph.D., CHU Lapeyronie and Montpellier University, Montpellier, France

Additional Data

Poster Presentations (All Times PST)

Monday, Nov. 6

- | Abstract 1001: 9:00-11:00 a.m.
 - | Persistence, Discontinuation, and Switching Patterns Among Ankylosing Spondylitis Patients Newly Initiating Biologic Therapy
 - | Presenter: Theresa Hunter, Eli Lilly and Company, Indianapolis, IN, United States
- | Abstract 1513: 9:00-11:00 a.m.
 - | Clinical Characteristics and Peripheral Joint Involvement at the Time of Diagnosis of Non-Radiographic Axial Spondyloarthritis Patients in the United States and Europe
 - | Presenter: David Sandoval, Eli Lilly and Company, Indianapolis, IN, United States
- | Abstract 1555: 9:00-11:00 a.m.
 - | Treatment Changes by Joint Activity and Skin Severity in Patients with Comorbid Active PsA and PsO
 - | Presenter: William Malatestinic, Eli Lilly and Company, Indianapolis, IN, United States

- ┆ Abstract 1842: 2:30-4:00 p.m.
 - ┆ Subsetting Systemic Lupus Erythematosus by Interferon Gene Signatures and Serologies (anti-dsDNA and Low Complement) Uncovers Significant Clinical Diversity
 - ┆ Presenter: Michelle Petri, M.D., M.P.H., Johns Hopkins University, Baltimore, MD, United States

Tuesday, Nov. 7

- ┆ Abstract 2532: 9:00-11:00 a.m.
 - ┆ The Relationship between the Degree of Skin Involvement and Joint Activity in Patients with PsA: Experience from the Corrona Registry
 - ┆ Presenter: William Malatestinic, Eli Lilly and Company, Indianapolis, IN, United States
- ┆ Abstract 2533: 9:00-11:00 a.m.
 - ┆ Current PsA Therapy Impacts the Relationship between the Degree of Skin Involvement and Joint Activity
 - ┆ Presenter: William Malatestinic, Eli Lilly and Company, Indianapolis, IN, United States
- ┆ Abstract 2539: 9:00-11:00 a.m.
 - ┆ The Contribution of Skin and Joint Improvements to the Health-Related Quality of Life of Patients with Active Psoriatic Arthritis
 - ┆ Presenter: Arthur Kavanaugh, M.D., University of California, San Diego, La Jolla, CA, United States
- ┆ Abstract 2549: 9:00-11:00 a.m.,
 - ┆ Achievement of Minimal Disease Activity Is Associated with Improvements in Health-Related Quality of Life and Productivity in Psoriatic Arthritis Patients
 - ┆ Presenter: Laura C. Coates, MBChB, MRCP, PhD, University of Leeds, Leeds, United Kingdom

INDICATIONS AND USAGE FOR TALTZ

Taltz[®] is indicated for the treatment of 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. 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 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. 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 ($> 1\%$) 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 Rheumatoid Arthritis

Rheumatoid arthritis is a systemic autoimmune disease characterized by inflammation and progressive destruction of joints.^{1,2} More than 23 million people worldwide suffer from RA.³ Approximately three times as many women as men have the disease. Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, oral conventional synthetic disease-modifying antirheumatic drugs (csDMARDs), such as methotrexate, and injectable, biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.⁴ Despite current treatment options, many patients do not reach their therapeutic goals or sustained remission.^{5,6} There remains an important need to provide additional treatments to improve overall patient care.

About Baricitinib

Baricitinib is a once-daily oral JAK inhibitor currently in clinical studies for inflammatory and autoimmune diseases. There are four known JAK enzymes: JAK1, JAK2, JAK3 and TYK2. JAK-dependent cytokines have been implicated in the pathogenesis of a number of inflammatory and autoimmune diseases, suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions, including rheumatoid arthritis.

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases. Baricitinib was submitted for regulatory review seeking marketing approval for the treatment of rheumatoid arthritis in the U.S., the European Union and Japan in 2016. Baricitinib was approved in the EU in February 2017 and in Japan in July 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for baricitinib. Baricitinib remains under review in other markets. It is also being studied for the treatment of atopic dermatitis and systemic lupus erythematosus. The Phase 3 program for psoriatic arthritis is expected to begin in 2018.

About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.⁷ 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.^{11,8} Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease.¹¹ The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.¹¹

About Active Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive form of inflammatory arthritis that can cause swelling, stiffness and pain in and around the joints, nail changes and impaired physical function.⁹ It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.¹⁰ Typically, psoriatic arthritis affects peripheral joints in the arms and legs (elbows, wrists, hands and feet), but can also affect joints in the axial skeleton (spine, hips and shoulders).¹¹ If left untreated, PsA can cause permanent joint damage.¹⁴ Additionally, up to 30 percent of people with psoriasis also develop PsA.¹⁴

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.

Lilly has filed a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for Taltz for the treatment of active PsA. Lilly also submitted Taltz to the European Medicines Agency (EMA) for the treatment for adult patients with active PsA. Taltz is approved for adult patients with active PsA in Japan. Submissions to other regulatory agencies around the world are expected later this year. Taltz is also in Phase 3 trials for the treatment of radiographic and non-radiographic axial spondyloarthritis.

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.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's web site at www.incyte.com.

Follow @Incyte on Twitter at <https://twitter.com/Incyte>.

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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 potential treatment for psoriatic arthritis and baricitinib as a potential treatment for patients with rheumatoid arthritis, and reflects Lilly's current belief. This press release also contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about baricitinib as a potential treatment for patients with rheumatoid arthritis, and reflects Lilly's and Incyte'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 or baricitinib will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte'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 and Incyte undertake no duty to update forward-looking statements to reflect events after the date of this release.

- 1 American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp. Accessed October 23, 2017.
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- 4 Arthritis Foundation, Medications for Rheumatoid Arthritis, <http://www.arthritisfoundation.org/about-arthritis/types-of-arthritis/rheumatoid-arthritis/treatment-plan/medication-overview/ra-medications.php>. Accessed October 23, 2017.
- 5 Rheumatoid arthritis, Lancet, <https://www.ncbi.nlm.nih.gov/pubmed/27156434>. Accessed October 23, 2017.
- 6 Sustained rheumatoid arthritis remission is uncommon in clinical practice, Arthritis Research & Therapy, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/>. Accessed October 23, 2017.
- 7 Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed October 23, 2017.
- 8 Psoriasis. American Academy of Dermatology website. <https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis>. Accessed October 23, 2017.
- 9 About psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis>. Accessed October 23, 2017.
- 10 What is psoriatic arthritis? Arthritis Foundation website. <http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php>. Accessed October 23, 2017.
- 11 Classification of psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis>. Accessed October 23, 2017.



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