



November 3, 2016

Lilly Presents Clinical Efficacy, Safety and Patient-Reported Outcomes Data of Baricitinib in Patients with Rheumatoid Arthritis at 2016 American College of Rheumatology Annual Meeting

- Lilly immunology portfolio to be featured in 23 presentations
- Presentations include real-world assessment of medication use and preferences among rheumatoid arthritis patients

INDIANAPOLIS, Nov. 3, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that new post-hoc analyses of pooled efficacy and safety data from baricitinib phase 3 studies, along with findings from a real-world assessment of medication use among rheumatoid arthritis (RA) patients and other phase 2 studies, will be presented at the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Meeting in Washington DC, November 11-16, 2016. Additionally, six abstracts, including one oral presentation, will feature results from pivotal phase 3 data of Taltz[®] (ixekizumab) for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis.

"The positive data to be presented at ACR provide further support for baricitinib as a potential treatment option for rheumatoid arthritis patients," said J. Anthony Ware, M.D., senior vice president, product development, Lilly Bio-Medicines. "We look forward to presenting these new results, along with other important data from our immunology portfolio, as we continue our work to address and alleviate unmet needs people living with chronic autoimmune diseases face."

Highlighted presentations and posters include:

Baricitinib

Sunday, November 13, 2016, 9:00am - 11:00am EST - POSTER PRESENTATIONS

- ┆ Biologic Initiation Patterns Among Rheumatoid Arthritis Patients in Moderate or High Disease Activity While Using Conventional Disease Modifying Anti-Rheumatic Drugs (Presenting Author: Boytsov, N.) Abstract Number: 637
- ┆ Drivers of the SLE Responder Index (SRI) Endpoint in Clinical Trials of SLE (Presenting Author: Kalunian, K.) Abstract Number: 784

Monday, November 14, 2016, 9:00am - 11:00am EST - POSTER PRESENTATIONS

- ┆ Baricitinib Exposure-Efficacy Relationship in Rheumatoid Arthritis Patients from Integrated Analyses of Phase 2 and Phase 3 Studies (Presenting Author: Ernest, C.) Abstract Number: 1584
- ┆ Previous Use of Conventional Disease-Modifying Antirheumatic Drugs and Response to Baricitinib (Presenting Author: Kavanaugh, A.) Abstract Number: 1585
- ┆ Efficacy and Safety of Baricitinib in Patients with Rheumatoid Arthritis and an Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs: A United States Subpopulation Analysis from Two Phase 3 Trials (Presenting Author: Wells, A.) Abstract Number: 1586
- ┆ Safety and Efficacy of Baricitinib in Elderly Patients with Moderate to Severe Rheumatoid Arthritis (Presenting Author: Fleischmann, R.) Abstract Number: 1590
- ┆ Efficacy and Safety of Switching from Adalimumab to Baricitinib: Phase 3 Data in Patients with Rheumatoid Arthritis (Presenting Author: Taylor, P.) Abstract Number: 1591
- ┆ Speed of Onset of Effect on Patient-Reported Outcomes Assessed through Daily Electronic Patient Diaries in the Baricitinib Phase 3 RA Clinical Program (Presenting Author: Taylor, P.) Abstract Number: 1599
- ┆ Effect of BMI on Baricitinib Efficacy: Pooled Analysis from Two Phase 3 Rheumatoid Arthritis Clinical Trials (Presenting Author: Zerbini, C.) Abstract Number: 1640

Tuesday, November 15, 2016, 9:00am - 11:00am EST - POSTER PRESENTATIONS

- ┆ Biologic DMARD Use Among U.S. Patients in an Online Rheumatoid Arthritis Community (Presenting Author: Chang, L.) Abstract Number: 2237

- | RA Medication Preferences Among U.S. Patients in an Online Rheumatoid Arthritis Community (Presenting Author: Zhu, B.) Abstract Number: 2238
- | DMARD, Biologic and Small Molecule Drug Use Among ACPA Positive and ACPA Negative RA Patients in a Tertiary Referral Center (Presenting Author: Meehan, R.) Abstract Number: 2496
- | Prevalence of Anemia Among Rheumatoid Arthritis Patients Treated With Conventional Disease-Modifying Antirheumatic Drugs (Presenting Author: Kay, J.) Abstract Number: 2584
- | Effects of Baseline Patient Characteristics on Baricitinib Efficacy in Patients with Rheumatoid Arthritis (Presenting Author: Kremer, J.) Abstract Number: 2632

Tuesday, November 15, 2016, 2:30pm - 4:30pm EST - ORAL PRESENTATIONS

- | A Molecular Signature Based on IFN Gene Signature and Serology Defines Two Populations of Patients with Different Baseline Disease Activity in a Large Multinational Phase 3 SLE Trial Population (Presenting Author: Petri, M.) Abstract Number: 2991
- | Lipid Profile and Effect of Statin Treatment in Pooled Phase 2 and Phase 3 Baricitinib Studies (Presenting Author: McInnes, I.) Abstract Number: 3023
- | Herpes Zoster in Patients with Moderate to Severe Rheumatoid Arthritis Treated with Baricitinib (Presenting Author: Winthrop, K.) Abstract Number: 3027

Taltz Data

Sunday, November 13, 2016, 2:30pm - 4:00pm EST - ORAL PRESENTATION

- | Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis: 52 week Results from a Phase 3 Study (Presenting Author: Mease, P.) Abstract Number: 959

Monday, November 14, 2016, 9:00am - 11:00am EST - POSTER PRESENTATIONS

- | Association of Early Skin Improvement with ACR Responses Among Biologic DMARD-Naive Psoriatic Arthritic Patients Treated with Ixekizumab (Presenting Author: Birt, J.) Abstract Number: 1686
- | Effect of Concomitant Conventional Disease-Modifying Antirheumatic Drugs (DMARDs) on the Efficacy and Safety of Ixekizumab in Biologic DMARD-Naive Patients with Active Psoriatic Arthritis (Presenting Author: Lin, C.) Abstract Number: 1687
- | Ixekizumab Provides Sustained Improvement up to 52 Weeks of Disease Activity as Assessed by Composite Measure Scores in Biologic Disease-Modifying Antirheumatic Drug -Naive Patients with Active Psoriatic Arthritis (Presenting Author: Coates, L.) Abstract Number: 1688
- | Ixekizumab Provides Improvements Through 52 Weeks in Physical Function, Quality of Life, and Work Productivity in Biologic Disease-Modifying Antirheumatic Drug-Naive Patients with Active Psoriatic Arthritis (Presenting Author: Gladman, D.) Abstract Number: 1689
- | Sustained Efficacy of Ixekizumab in Patients with Moderate-to-Severe Plaque Psoriasis and Concomitant Psoriatic Arthritis (Presenting Author: Burge, R.) Abstract Number: 1733

Indications and Usage

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

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. 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.

IX HCP ISI 22MAR2016

About Baricitinib

Baricitinib is a once-daily oral selective JAK1 and JAK2 inhibitor currently in late-stage 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. Baricitinib demonstrates approximately 100-fold greater potency of inhibition against JAK1 and JAK2 than JAK3 in kinase assays.

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., European Union and Japan in Q1 2016, and is being studied in phase 2 trials for atopic dermatitis and systemic lupus erythematosus.

About Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease characterized by inflammation and progressive destruction of joints.^{i,ii} More than 23 million people worldwide suffer from RA.ⁱⁱⁱ 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 disease-modifying antirheumatic drugs (cDMARDs), such as methotrexate - the current standard of care - and injectable, biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.^{iv} Despite current treatment options, many patients do not reach their therapeutic goals or sustained remission.^{v,vi} There remains an important need to provide additional treatments to improve overall patient care.

About Taltz[®]

Taltz[®] (ixekizumab) is a humanized 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. Ixekizumab inhibits the release of pro-inflammatory cytokines and chemokines. Taltz is in clinical development for the treatment of psoriatic arthritis and axial spondyloarthritis.

About Psoriatic Arthritis

Psoriatic arthritis is a progressive, chronic disease that can cause swelling, stiffness and pain in and around the joints, nail changes and impaired physical function.^{vii,viii} Not everyone who has psoriasis will develop psoriatic arthritis; however, approximately 30 percent of people with psoriasis may also develop psoriatic arthritis.^{ix}

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 baricitinib as a potential treatment for patients with rheumatoid arthritis and ixekizumab as a treatment for psoriasis and psoriatic arthritis, 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 future study results will be consistent with the results to date or that baricitinib or ixekizumab will achieve its primary study endpoints or receive regulatory approvals. 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.

ⁱ American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp. Accessed May 16, 2016.

ⁱⁱ Hand Clinics, *Advances in the Medical Treatment of Rheumatoid Arthritis*, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf>. Accessed May 16, 2016.

ⁱⁱⁱ WHO Global Burden of Disease Report, (table 7, page 32) 2004, http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed May 16, 2016.

^{iv} 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 May 16, 2016.

^v Rheumatoid arthritis, *Lancet*, <https://www.ncbi.nlm.nih.gov/pubmed/27156434>. Accessed May 19, 2016 .

^{vi} Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/>. Accessed May 19, 2016.

^{vii} Gladman D, Antoni C, et. al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Annals of the Rheumatic Diseases*. 2005;64(2):ii14-ii17.

^{viii} Psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis>. Accessed September 27, 2016.

^{ix} What is psoriatic arthritis? Arthritis Foundation website. <http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php>. Accessed September 27, 2016.

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The Lilly logo is a stylized, red, cursive script of the word "Lilly". The letters are thick and fluid, with a prominent 'L' and a long, sweeping tail on the 'y'.



Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

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