



June 7, 2016

Results of Clinical and Patient-Reported Outcomes Data for Baricitinib in Patients with Rheumatoid Arthritis to be Presented at Annual European Congress of Rheumatology (EULAR 2016)

Lilly immunology portfolio to be featured in 16 presentations

INDIANAPOLIS, June 7, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that radiographic results from a long-term extension study of baricitinib, RA-BEYOND, and patient-reported outcomes data from baricitinib's phase 3 global studies will be presented, along with other phase 2b and preclinical studies, at the Annual European Congress of Rheumatology (EULAR 2016) in London, June 8-11, 2016.

"We look forward to presenting new data from our immunology portfolio at the Annual European Congress of Rheumatology (EULAR 2016)," said J. Anthony Ware, M.D., senior vice president, product development, Lilly Bio-Medicines. "Lilly is committed to developing the next generation of treatments, especially for people with rheumatoid arthritis and psoriatic arthritis because these patients deserve new alternative treatment options."

Highlighted presentations and posters include:

Baricitinib Data

Thursday, June 9, 2016, 11:45am - 1:30pm BST - POSTER PRESENTATIONS

- | Safety Profile of Baricitinib in Patients with Active RA: An Integrated Analysis (Presenting Author: Smolen, J.) Abstract Number: THU0166
- | Baricitinib Inhibits Radiographic Progression of Structural Joint Damage at 1 Year in Patients with Rheumatoid Arthritis (RA) and An Adequate Response to csDMARDs (Presenting Author: van der Heijde, D.) Abstract Number: THU0168
- | Ex Vivo Functional Comparison of Baricitinib and Tofacitinib for Cytokine Signaling in Human Leukocyte Subpopulations (Presenting Author: McInnes, I.) Abstract Number: THU0182
- | Response to Baricitinib at 4 Weeks Predicts Response at 12 and 24 Weeks in Patients with Rheumatoid Arthritis: Results from Two Phase 3 Studies (Presenting Author: Weinblatt, M.) Abstract Number: THU0193
- | Baricitinib Effects on Lipid and NMR-Measured Lipoprotein Profiles in a Phase 3 Study in Patients with Rheumatoid Arthritis (Presenting Author: Taylor, P.) Abstract Number: THU0198
- | Weak Correlation Between a Multi-Biomarker Disease Activity Score and Clinical Response with Baricitinib in a Phase 2b Study in Rheumatoid Arthritis (Presenting Author: Fleischmann, R.) Abstract Number: THU0201
- | Characterization of Changes in Lymphocyte Subsets in Baricitinib-Treated Patients with Rheumatoid Arthritis in a Phase 3 Study (RA-BEAM) (Presenting Author: Tanaka, Y.) Abstract Number: THU0209
- | Patient-Reported Outcomes from a Phase 3 Study of Baricitinib Versus Placebo or Adalimumab in Patients with Active Rheumatoid Arthritis and an Inadequate Response to Background Methotrexate Therapy (Presenting Author: Keystone, E.) Abstract Number: THU0609
- | Work Productivity and Daily Activity in Patients with Rheumatoid Arthritis in Four Phase 3 Randomized Clinical Trials of Baricitinib (Presenting Author: Smolen, J.S.) Abstract Number: THU0617
- | Patient-Reported Outcomes from a Phase 3 Study of Baricitinib in Patients with Early Rheumatoid Arthritis who had Received Limited or no Treatment with Disease-Modifying Anti-Rheumatic Drugs (Presenting Author: Schiff, M.) Abstract Number: THU0623

Friday, June 10, 2016, 11:10am - 11:20am BST - ORAL PRESENTATION

- | Baricitinib Dose Step-Down Following Disease Control in Patients with Rheumatoid Arthritis (Presenting Author: Takeuchi, T.) Abstract Number: OP0228

Friday, June 10, 2016, 11:15am - 1:30pm BST - POSTER PRESENTATION

- | Influence of Route of Administration/Drug Formulation and Other Factors on Compliance with Treatment in Rheumatoid Arthritis and Dyslipidaemia (Presenting Author: Fautrel, B.) Abstract Number: FRI0565

Ixekizumab Data

Thursday, June 9, 2016, 11:45am - 1:30pm BST - POSTER PRESENTATIONS

- ▮ Ixekizumab Provides Improvements Through 52 Weeks in Physical Function, Quality of Life, and Work Productivity in Biologic Disease-Modifying Antirheumatic Drug-Naïve Patients with Active Psoriatic Arthritis (Gottlieb, A.B.) Abstract Number: THU0430
- ▮ Ixekizumab Provides Sustained Improvement up to 52 Weeks of Disease Activity as Assessed by Composite Measure Scores in Biologic Disease-Modifying Antirheumatic Drug (bDMARD)-Naïve Patients with Active Psoriatic Arthritis (Coates, L.C.) Abstract Number: THU0440
- ▮ Effect of Concomitant Conventional Disease-Modifying Antirheumatic Drugs (DMARDs) on the Efficacy and Safety of Ixekizumab in Biologic DMARD-Naïve Patients with Active Psoriatic Arthritis (Presenting Author: Coates, L.C.) Abstract Number: THU0441

Friday, June 10, 2016, 10:30am - 10:40am BST - ORAL PRESENTATION

- ▮ Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis: 52 week Results from a Phase 3 Study (SPIRIT-P1) (Presenting Author: Mease, P.J.) Abstract Number: OP0109

About Baricitinib

Baricitinib is a once-daily oral highly 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,iii] 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 Ixekizumab

Ixekizumab is a humanised IgG4 monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor.^[vii] IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.^[vii] Ixekizumab inhibits the release of pro-inflammatory cytokines and chemokines.^[ix] Ixekizumab is in clinical development for the treatment of psoriatic arthritis and axial spondyloarthritis.

About Psoriatic Arthritis

Psoriatic arthritis 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. If left untreated, psoriatic arthritis can cause permanent joint damage. Up to 30 percent of people with psoriasis also develop psoriatic arthritis.^[x]

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.

(P-LLY)

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 treatment for rheumatoid arthritis and ixekizumab as a treatment for psoriatic arthritis, and reflects Lilly's current beliefs. 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 study findings to-date, or that baricitinib or ixekizumab will receive regulatory approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent 10-K and 10-Q filings with the United States Securities and Exchange Commission. Except as may be required by law, Lilly undertakes no duty to update forward-looking statements for events occurring 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](http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf) 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.arthritisday.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} Data on File. Eli Lilly and Company; 2015

^{viii} Moderate to severe psoriasis and psoriatic arthritis: biologic drugs. National Psoriasis Foundation website

^{ix} Lønnberg AS, Zachariae C, Skov L. Targeting of interleukin-17 in the treatment of psoriasis. *Clinical, Cosmetic and Investigational Dermatology*. 2014;7:251-259.doi:10.2147/CCID.S67534

^x About psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis> (Accessed: May 16, 2016)

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/results-of-clinical-and-patient-reported-outcomes-data-for-baricitinib-in-patients-with-rheumatoid-arthritis-to-be-presented-at-annual-european-congress-of-rheumatology-eular-2016-300280556.html>

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