November 4, 2015

Results of Two Pivotal Baricitinib Trials to be Presented at 2015 American College of Rheumatology Annual Meeting

Lilly immunology portfolio to be featured in 12 presentations

INDIANAPOLIS, Nov. 4, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announces that detailed data for two phase 3 pivotal trials of the investigational medicine baricitinib in rheumatoid arthritis, RA-BEGIN and RA-BEAM, will be presented at the American College of Rheumatology/Association of Rheumatology Health Professionals annual meeting in San Francisco, November 6-11, 2015. Detailed results from a phase 3 study of ixekizumab in psoriatic arthritis will also be presented at the conference.

"Lilly is committed to raising expectations for people living with some of the world's most debilitating chronic conditions, including rheumatoid arthritis and psoriatic arthritis," said J. Anthony Ware, M.D., senior vice president, product development, Lilly Bio-Medicines. "We look forward to presenting these compelling data from our immunology portfolio, which exemplify Lilly's progress in advancing the treatment of these diseases."

Highlighted presentations and posters include:

Baricitinib Data

Sunday, November 8, 2015, 9:00am-11:00am PT - Poster Session A

- Evaluate the Dose Efficacy Response Relationship of Baricitinib in Patients with Rheumatoid Arthritis (Presenting Author: Zhang, X.) Abstract Number 485

Sunday, November 8, 2015, 4:30pm-6:00pm PT - Concurrent Abstract Session

- Baricitinib, Methotrexate, or Baricitinib Plus Methotrexate in Patients with Early Rheumatoid Arthritis Who Had Received Limited or No Treatment with Disease-Modifying Anti-Rheumatic Drugs (DMARDs): Phase 3 Trial Results (Presenting Author: Fleischmann, R.) Abstract Number 1045
- Previous Biologic Disease-Modifying Antirheumatic Drug (bDMARD) Exposure and Efficacy and Safety Analysis from a Phase 3 Study of Baricitinib in Patients with Rheumatoid Arthritis and an Inadequate Response to Tumor Necrosis Factor Inhibitors (Presenting Author: Genovese, M.) Abstract Number 1046
- Characterization of Changes in Lymphocyte Subsets in Baricitinib-Treated Patients with Rheumatoid Arthritis in Two Phase 3 Studies (Presenting Author: Emery, P.) Abstract Number 1047
- 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: Kremer, J.) Abstract Number 1050

Monday, November 9, 2015, 9:00am-11:00am PT - Poster Session B

- TNFi Combination Therapy, Switching and Persistence Patterns By Longitudinal Disease Activity Strata in Patients with Rheumatoid Arthritis (Presenting Author: Harrold, L.) Abstract Number 1637

Tuesday, November 10, 2015, 9:00am-11:00am PT - Poster Session C

- Patient-Reported Outcomes from a Phase 3 Study of Baricitinib in Patients with Rheumatoid Arthritis with Inadequate Response to Conventional Synthetic Disease-Modifying Antirheumatic Drugs (Presenting Author: Emery, P.) Abstract Number 2730

Tuesday, November 10, 2015, 4:45pm PT - Latebreaker Abstract Session

- Baricitinib Versus Placebo or Adalimumab in Patients with Active Rheumatoid Arthritis (RA) and an Inadequate Response to Background Methotrexate Therapy: Results of a Phase 3 Study (Presenting Author: Taylor, P.) Abstract Number 2L

Ixekizumab Data

Sunday, November 8, 2015, 2:30pm-4:00pm PT - Concurrent Abstract Session

- A Randomized, Double-Blind, Active- and Placebo-Controlled Phase 3 Study of Efficacy and Safety of Ixekizumab, Adalimumab, and Placebo Therapy in Patients Naïve to Biologic Disease Modifying Anti-Rheumatic Drugs with Active Psoriatic Arthritis (Presenting Author: Mease, P.) Abstract Number 977

Monday, November 9, 2015, 4:30pm-6:00pm PT - Concurrent Abstract Session

- Ixekizumab Improves Physical Function, Quality of Life, and Work Productivity in Biologic Disease-Modifying Antirheumatic Drug-Naive Patients with Active Psoriatic Arthritis (Presenting Author, Gottlieb, A.) Abstract Number 2145

Tabalumab Data

Sunday, November 8, 2015, 4:30pm-6:00pm PT - Concurrent Abstract Session

- Baseline Gene Expression Profiles in 1760 Patients from Two Phase III Trials of BAFF/BLyS Blockade in SLE (Presenting Author, Hoffman, R.) Abstract Number 1072

Tuesday, November 10, 2015, 9:00am-11:00am PT - Poster Session C

- The Impact of Tabalumab on the Kidney in Systemic Lupus Erythematosus: Results from Two Phase 3 Randomized Clinical Trials (Presenting Author: Dooley, M.) Abstract Number 2939

About Baricitinib
Baricitinib is the only 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 JAK 3 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 is currently in phase 3 clinical development for rheumatoid arthritis and phase 2 development for psoriasis, diabetic nephropathy and atopic dermatitis.

About Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease[i] characterized by inflammation and progressive destruction of joints.[ii] More than 23 million people worldwide suffer from RA.[iii] Approximately three times as many women as men have the disease. Patients and physicians indicate there remains an important opportunity to improve patient care. Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, oral disease-modifying anti-rheumatic drugs such as methotrexate, and injectable biological response modifiers that target selected mediators implicated in the pathogenesis of RA.[iv]

About Ixekizumab
Ixekizumab is a monoclonal antibody with high affinity and specificity that binds to and neutralizes the pro-inflammatory cytokine interleukin-17A (IL-17A). In psoriasis, IL-17A plays a major role in driving excess keratinocyte (skin cell) proliferation and activation. Ixekizumab does not bind to cytokines IL-17B, IL-17C, IL-17D, IL-17E or IL-17F. Ixekizumab is administered via subcutaneous injection (under the skin). Ixekizumab is also in clinical development for the treatment of psoriatic arthritis.

About Psoriatic Arthritis
Psoriatic arthritis is a chronic joint disease characterized by both psoriasis and a related form of inflammatory arthritis that causes pain, stiffness and swelling in and around the joints. Not everyone who has psoriasis will develop psoriatic arthritis; however, up to 30 percent of people with psoriasis may develop psoriatic arthritis during the course of their disease.

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 Lilly's product pipeline and reflects Lilly's current beliefs. However, there are substantial risks and uncertainties in the process of pharmaceutical research, development, and commercialization. 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: Oct. 26, 2015)

[ii] Hand Clinics, *Advances in the Medical Treatment of Rheumatoid Arthritis*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf (Accessed: Oct. 26, 2015)

[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 Oct. 26, 2015)

[iv] Arthritis Foundation, Medications for Rheumatoid Arthritis, http://www.arthritistoday.org/about-arthritis/types-of-arthritis/rheumatoid-arthritis/treatment-plan/medication-overview/ra-medications.php (Accessed: Oct. 26, 2015)

Refer to: Celeste Stanley; celeste_stanley@lilly.com; +1-317-626-8896 (media)
Phil Johnson; johnson_philip_l@lilly.com; +1-317-655-6874 (investors)

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