Lilly and Incyte unveil detailed data on two pivotal studies of baricitinib in rheumatoid arthritis

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EULAR congress in Rome will be first public presentations of Phase 3 data

INDIANAPOLIS, June 10, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announced that five abstracts featuring data from three clinical studies and separate pharmacology studies for its investigational rheumatoid arthritis drug baricitinib will be presented at the 2015 annual meeting of the European League Against Rheumatism in Rome June 10-13. Lilly and Incyte previously released positive topline results for the RA-BEACON and RA-BUILD studies, both of which met their primary endpoint of ACR20 at 12 weeks as compared to placebo.

"Incyte is committed to translating R&D excellence into new medicines, and we are very pleased with the initial results from the Phase 3 trials program of baricitinib," said Rich Levy, M.D., chief drug development officer at Incyte Corporation.

"With the prevalence of rheumatoid arthritis worldwide, Lilly is excited to share further information about baricitinib with the scientific community,"said David Ricks, Lilly senior vice president, and president of Lilly Bio-Medicines. "Lilly remains committed to following the science to challenge convention and continuously improve outcomes."

Abstracts being presented are highlighted below or can be accessed on the EULAR website at http://www.congress.eular.org.

- "Baricitinib, An Oral Janus Kinase (JAK)1/JAK2 Inhibitor, In Patients With Active Rheumatoid Arthritis (RA) And An Inadequate Response To TNF Inhibitors: Results Of The Phase 3 RA-BEACON Study" - M. Genovese
- "Baricitinib, an Oral JAK1/JAK2 Inhibitor, in Patients With Active Rheumatoid Arthritis and an Inadequate Response to cDMARDs: Results of the Phase 3 RA-BUILD Study" - M. Dougados
- "Effects Of Baricitinib On Multi Biomarker Disease Activity Scores And Their Components In A Phase 2b Study In Moderate-To-Severe Rheumatoid Arthritis Patients" - P. Taylor
- "Effects Of Baricitinib, An Oral JAK1/JAK2 Inhibitor, On Patient-Reported Outcomes From A Phase 3 Study In Patients Who Have Had An Inadequate Response To Tumor Necrosis Factor Inhibitors" - J.S. Smolen
- "Evaluation Of Potential Drug-Drug Interactions With Baricitinib" - C. Payne

About Baricitinib
Baricitinib is a once daily, oral, selective JAK1 and JAK2 inhibitor. 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 and diabetic nephropathy.

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 Baricitinib Phase 3 Trials
Lilly and Incyte are conducting four pivotal Phase 3 clinical trials of baricitinib in patients with moderately-to-severely active rheumatoid arthritis to support regulatory submission in most countries. An additional Phase 3 study was initiated to support clinical development in China. The clinical trial program includes a wide range of patients including those who are methotrexate naïve, inadequate responders to methotrexate, inadequate responders to conventional disease-modifying anti-rheumatic drugs, or inadequate responders to TNF inhibitors. Four of these five pivotal studies are expected to be completed by the end of 2015. Patients completing any of the five Phase 3 studies can enroll in a long-term extension study. For additional information on this clinical trial program, please visit www.clinicaltrials.gov.

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

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 about baricitinib as a potential treatment for patients with rheumatoid arthritis and reflects Lilly

and Incyte's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results will be consistent with study findings to-date, or that baricitinib will receive regulatory approval. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's filings with the United States Securities and Exchange Commission. Lilly and Incyte undertake no duty to update forward-looking statements.

[i] American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp (Accessed: October 27, 2014)
[ii] Hand Clinics, *Advances in the Medical Treatment of Rheumatoid Arthritis*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf (Accessed: October 27, 2014)
[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 Nov. 11, 2014)
[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: May 15, 2013)

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