December 9, 2014

Lilly and Incyte Announce Positive Top-Line Results From Phase 3 Trial of Baricitinib in Moderate to Severe Rheumatoid Arthritis

FIRST OF SEVERAL PHASE 3 TRIALS TO REPORT RESULTS

INDIANAPOLIS, Dec. 9, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announce that the Phase 3 RA-BEACON study of the investigational medicine baricitinib met its primary endpoint of improved ACR20 response compared to placebo after 12 weeks of treatment. The study included patients with moderately-to-severely active rheumatoid arthritis (RA) who previously failed one or more tumor necrosis factor (TNF) inhibitors and who were taking stable doses of conventional disease-modifying anti-rheumatic drug (cDMARD) therapy. The companies will share results of several ongoing Phase 3 studies in various disclosures in 2015.

"People with rheumatoid arthritis who have had an inadequate response to TNF inhibitors are generally considered to be the least responsive to subsequent treatments," said David Ricks, Lilly senior vice president, and president, Lilly Bio-Medicines. "These results give us further confidence in the potential for baricitinib to be a meaningful treatment option for those suffering from this debilitating condition."

"We are very pleased by these results," said Rich Levy, M.D., chief drug development and medical officer, Incyte Corporation. "Over the next 12 months we look forward to seeing the data from additional Phase 3 studies of baricitinib in rheumatoid arthritis, including patients who have had an inadequate response to conventional DMARDs and in those with earlier stage disease."

The RA-BEACON study enrolled 527 patients who had previously failed at least one anti-TNF therapy, and included a high percentage who had also received prior treatment with one or several non-anti-TNF biologic agents. Patients received either 1 of 2 doses of once daily baricitinib or placebo in addition to their background conventional disease-modifying anti-rheumatic drug therapy (cDMARDs).

The incidence of serious adverse events with baricitinib treatment, including serious infections, was similar to placebo. There were no opportunistic infections or gastrointestinal perforations in the study. A higher incidence of treatment-emergent adverse events was observed with baricitinib compared to placebo. The most common adverse events observed with baricitinib were headache, upper respiratory tract infection and nasopharyngitis. Discontinuation rates due to adverse events were similar between treatment groups. A large majority of patients completing this 6-month trial opted to participate in a long-term extension study.

Detailed data from the RA-BEACON study will be presented at scientific meetings in 2015. Lilly and Incyte are evaluating the safety and efficacy of baricitinib in an extensive Phase 3 program with a total enrollment of over 3,000 people with rheumatoid arthritis.

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 (RA) 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 recently 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 small molecule drugs 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).

Contact:

Celeste Stanley
+1 (317) 626-8896
Email: celeste_stanley@lilly.com

Pam Murphy
+1 (302) 498-6944
Email: pmurphy@incyte.com

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

Logo - http://photos.prnewswire.com/prnh/20141208/163029LOGO

PDF - http://origin-qps.onstreammedia.com/origin/multivu_archive/ENR/Lilly_v12_infographic.pdf

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/lilly-and-incyte-announce-positive-top-line-results-from-phase-3-trial-of-baricitinib-in-moderate-to-severe-rheumatoid-arthritis-300006676.html

SOURCE Eli Lilly and Company; Incyte Corporation