Baricitinib Superior to Placebo in Reducing Rheumatoid Arthritis Disease Activity in Second Phase 3 Study

February 23, 2015

INDIANAPOLIS, Feb. 23, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announce that the investigational medicine baricitinib demonstrated a statistically significant improvement compared to placebo in a second consecutive Phase 3 trial in rheumatoid arthritis (RA). The RA-BUILD study included patients with moderately-to-severely active rheumatoid arthritis who had an inadequate response to, or were intolerant of, at least one conventional disease-modifying antirheumatic drug (cDMARD). The study met its primary endpoint of an improved ACR20 response rate compared to placebo after 12 weeks of treatment.

"We are encouraged that baricitinib demonstrated statistically significant improvement in rheumatoid arthritis disease activity compared to placebo, now in a second pivotal study," said David Ricks, Lilly senior vice president, and president of Lilly Bio-Medicines.

Part of an extensive Phase 3 program testing baricitinib in more than 3,000 patients at different stages along the RA treatment continuum, the RA-BUILD study enrolled 684 patients with rheumatoid arthritis who previously had an inadequate response to, or were intolerant of, at least one cDMARD and had not received a biologic disease-modifying antirheumatic drug (bDMARD). Patients received either one of two doses of once-daily baricitinib or placebo, in addition to their background therapy.

"Despite treatment advances, many people with RA continue to experience active disease, including pain, joint stiffness, disability and progressive joint damage," said Rich Levy, M.D., chief drug development and medical officer, Incyte Corporation. "These results suggest that baricitinib could provide an additional treatment option for patients who are not responding to conventional drugs."

In RA-BUILD, the incidence of treatment-emergent adverse events and 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 single case of tuberculosis was reported in a patient receiving baricitinib. The most common adverse events observed were consistent with previous studies of baricitinib in RA. 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.

Lilly and Incyte announced top-line results from the first Phase 3 trial of baricitinib, RA-BEACON, which also met its primary endpoint, in December 2014 and plan to present detailed data from both RA-BEACON and RA-BUILD at scientific meetings in 2015.

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 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 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).

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

Michael Booth, DPhil
+1 (302) 498-5914
Email: mbooth@incyte.com

Logo - http://photos.prnewswire.com/prnh/20031219/LLYLOGO
Logo - http://photos.prnewswire.com/prnh/20120608/DE21226LOGO
PDF - http://origin-qps.onstreammedia.com/origin/multivu_archive/ENR/Lilly-RA-Infographic-1.pdf

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/baricitinib-superior-to-placebo-in-reducing-rheumatoid-arthritis-disease-activity-in-second-phase-3-study-300039305.html

SOURCE Eli Lilly and Company; Incyte Corporation