Baricitinib Demonstrates Superiority to Adalimumab in Improving Signs and Symptoms of Rheumatoid Arthritis in Pivotal Phase 3 Study

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INDIANAPOLIS, Oct. 14, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announced positive topline results of RA-BEAM, the fourth successful Phase 3 study of baricitinib, an investigational medicine for patients with moderately-to-severely active rheumatoid arthritis.

The study met its primary objective of demonstrating superiority compared to placebo after 12 weeks of treatment based on ACR20 response – a standard clinical measure that represents at least a 20 percent improvement in RA disease activity. Baricitinib was also superior to adalimumab on key secondary objectives of ACR20 response and improvement in DAS28-hsCRP score after 12 weeks of treatment. Following 24 weeks of treatment, baricitinib was superior to placebo in preventing progressive radiographic structural joint damage. These treatment benefits with baricitinib observed at 12 and 24 weeks were maintained through 52 weeks of therapy.

"RA-BEAM is the first study to demonstrate that a once-daily oral treatment was superior in improving signs and symptoms of rheumatoid arthritis compared to the current injectable standard of care," said David Ricks, Lilly senior vice president, and president, Lilly Bio-Medicines. "If approved, baricitinib could help change expectations for people living with this debilitating disease."

"Combined results of these four Phase 3 studies give us confidence that, if approved, baricitinib could represent a valuable new treatment option for patients with RA," said Rich Levy, M.D., chief drug development officer, Incyte Corporation.

RA-BEAM evaluated the safety and efficacy of baricitinib in patients with active disease despite treatment with methotrexate, compared to placebo for 24 weeks or adalimumab (Humira®)* for 52 weeks. Part of a larger Phase 3 program of more than 3,000 RA patients at various points in the RA treatment continuum, RA-BEAM enrolled more than 1,300 patients who were randomized to one of three treatment groups:

- 4 mg oral once-daily baricitinib on background methotrexate
- 40 mg injectable every-other-week adalimumab on background methotrexate
- placebo on background methotrexate

Compared to placebo, serious adverse events rates were similar for baricitinib and lower for adalimumab; serious infection rates were similar across groups. There were no cases of gastrointestinal perforations. One event of tuberculosis was reported in each of the baricitinib and adalimumab groups. Rates of treatment-emergent adverse events, including infections, were higher for baricitinib and adalimumab compared to placebo. The most common adverse events observed with baricitinib were nasopharyngitis and bronchitis. Discontinuations due to adverse events occurred with similar frequency across treatment groups. A large majority of patients completing this trial opted to participate in a long-term extension study.

Lilly and Incyte announced top-line results in December 2014 for the first Phase 3 trial of baricitinib, RA-BEACON, and in February 2015 for the second, RA-BUILD. Data from these studies were presented at the EULAR annual scientific congress in June 2015. Topline results of the third Phase 3 trial, RA-BEGIN, were announced in September 2015 and will be presented at the American College of Rheumatology annual scientific congress in November. The companies plan to submit detailed data from RA-BEAM and other Phase 3 studies for presentation at scientific meetings and publication in peer-reviewed journals in 2015 and 2016.

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 have conducted 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 and remains ongoing. 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. 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
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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 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 approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's Form 10-K and 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly and Incyte undertake no duty to update forward-looking statements to reflect events 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: 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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