November 13, 2012

Lilly and Incyte Announce Additional Phase IIb Baricitinib Data, Including MRI Results, in Patients with Rheumatoid Arthritis

- Baricitinib advancing into Phase III trials for rheumatoid arthritis -
Lilly and Incyte to host a webcast for investors featuring these results today, Nov. 13 at 7 p.m. ET

WASHINGTON, Nov. 13, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (Nasdaq: INCY) today announced 24-week results from the continuation of an ongoing Phase IIb study of baricitinib, an orally available janus kinase (JAK) inhibitor, in patients with moderate-to-severe rheumatoid arthritis (RA) who had an inadequate response to treatment with methotrexate. Additionally, Magnetic Resonance Imaging (MRI) technology was used in a sub-study to examine the effect of baricitinib on joint erosion and other markers of structural changes in and around the joint. The findings were presented at the annual meeting of the American College of Rheumatology (ACR) in Washington, D.C.

Positive results of the placebo-controlled 12-week portion of the study were presented at the European League Against Rheumatism's (EULAR) Annual European Congress of Rheumatology in June 2012.[1] Patients taking baricitinib 4 mg or 8 mg once daily reported significant differences in ACR20, ACR50 and ACR70 responses compared with patients taking placebo. Data from the 12- to 24-week portion of the study, which did not include a placebo control, showed that patients who continued to receive 2 mg, 4 mg or 8 mg baricitinib once daily doses maintained or improved ACR20, ACR50 and ACR70 responses. The following chart defines the percentage of patients that achieved ACR20, ACR50 and ACR70 at 24 weeks of treatment with baricitinib.

Response at 24 weeks	2 mg (n=52)	4 mg (n=52)	8 mg (n=50)
ACR20	63	78	73
ACR50	20	48	55
ACR70	10	28	24

"These data are important because collectively they show patients experienced improvement with baricitinib as early as week two that was sustained through week 24," said Mark Genovese, M.D., the James Raitt professor of medicine and co-chief, division of immunology and rheumatology at Stanford University School of Medicine in Palo Alto, Calif., and steering committee member for the study. "Also of note is that the percentage of patients achieving ACR50 and ACR70 increased over time and no unexpected safety findings emerged with continued dosing."

Also Presented: MRI Findings
The study also included a large sub-study of 154 patients using Magnetic Resonance Imaging to examine the effect of different doses of baricitinib on joint changes in a subgroup of patients with erosive RA and inadequate response to treatment with methotrexate. There was statistically significant improvement in both the Total Inflammation Score and the Total Joint Damage Score for both 4 mg and 8 mg baricitinib doses compared with placebo at 12 weeks. The effects persisted through 24 weeks.

"This sub-study illustrates not only the efficacy of oral baricitinib in suppressing joint damage in RA, but also the power of MRI to demonstrate therapeutic effects in RA on synovitis, osteitis, bone erosion and even articular cartilage loss far more quickly (within only 12 weeks) and with far fewer patients than would be needed with conventional radiography," said Charles Peterfy, M.D., Ph.D., president and CEO of Spire Sciences LLC, who performed the image analyses.

"We believe the janus kinase inhibitors are an innovative class of molecules which we hope have the potential to improve outcomes for patients with diseases such as rheumatoid arthritis. We are very encouraged about the results for baricitinib, which represent the first 24-week clinical data for a selective JAK1 and JAK2 inhibitor in RA," said Eiry Roberts, M.D., vice president of autoimmune product development at Lilly. "Based on the benefit/risk data from the Phase II program for baricitinib, we recently moved ahead with Phase III clinical trials in RA."

Safety Results
In the 12-week portion of the study, the most common treatment-emergent adverse event (TEAE) class was infections, with a similar rate observed among patients in the placebo group (12 percent) and patients receiving baricitinib (14 percent).

Over 24 weeks in the combined 2 mg, 4 mg and 8 mg groups, the rate of TEAEs was 64 percent (36 percent mild, 23 percent

moderate, 5 percent severe) and the rate of serious adverse events was 5 percent.

There were no opportunistic infections and no deaths reported through week 24. Dose-dependent changes in laboratory tests (hemoglobin, lymphocyte and neutrophil count, low-density lipoprotein and high-density lipoprotein) were observed, with greater changes being observed in the 8 mg baricitinib group than in the 2 mg and 4 mg groups.

Trial Design and Status
This Phase IIb randomized double-blind, placebo-controlled, dose-ranging study, known as JADA, included 301 patients with moderate-to-severe RA with inadequate response to treatment with methotrexate.

In the initial 12-week treatment duration, patients received one of four doses of baricitinib or placebo. In the 12- to 24-week portion of the study, patients initially randomized to placebo or the 1 mg baricitinib dose were re-randomized to receive either 4 mg once daily or 2 mg twice daily for an additional 12 weeks; patients initially randomized to the 2 mg, 4 mg and 8 mg doses continued therapy with those doses. Patients are continuing to participate in the open-label long-term extension phase of the trial.

About JAK Inhibition
There are four known JAK enzymes: JAK1, JAK2, JAK3 and TYK2. These enzymes are critical components of signaling mechanisms used by a number of cytokines and growth factors, including those that are elevated in RA patients. Cytokines such as interleukin-6, -12 and -23 and both type 1 and type 2 interferons signal through the JAK/STAT pathways. Additional JAK-dependent cytokines also have been implicated in a number of inflammatory and autoimmune diseases, suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions.

About Baricitinib
Baricitinib is an orally administered selective JAK1 and JAK2 inhibitor that spares JAK3. Baricitinib is advancing into Phase III development as a potential treatment for rheumatoid arthritis and it is in Phase II development as a potential treatment for psoriasis and diabetic nephropathy.

Four Phase III RA studies are planned, which will investigate the safety and efficacy of baricitinib 2 mg and 4 mg once daily in patients with active RA who are methotrexate-naive, biologic-naive or biologic-experienced. Patients completing any of the four studies will be eligible for enrollment in a fifth study, a long-term extension.

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 inflammatory and autoimmune diseases.

About Rheumatoid Arthritis
Rheumatoid arthritis is characterized by abnormal immune mechanisms that lead to joint inflammation and swelling with progressive destruction of joints. In addition to affecting the joints, RA also can affect connective tissue in the skin and organs of the body.[2]

Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, oral disease-modifying antirheumatic drugs such as methotrexate, and injectable biological response modifiers that target tumor necrosis factor, a pro-inflammatory cytokine implicated in the pathogenesis of RA.

About the Webcast
Lilly and Incyte are hosting an investor meeting to discuss the baricitinib Phase II RA data presented at ACR. The presentation will be webcast live at 7 p.m. ET on Nov. 13, 2012 and will be available as a replay on both Lilly's website at http://investor.lilly.com/events.cfm and Incyte's website at http://www.incyte.com/ under Investor Relations, Events and Webcasts.

About Eli Lilly and Company
Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at http://www.lilly.com/.

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 website at http://www.incyte.com/.

This press release contains certain 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 and patient experience will be consistent with study findings to date or that the product will be commercially successful. 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.

P-LLY

[1] Edward Keystone, "Safety and Efficacy of LY3009104 (JAK1/JAK2 inhibitor) in RA Patients with Inadequate Response to MTX" (presented at the Annual European Congress of Rheumatology, presented by the European League Against Rheumatism, Berlin, Germany, June 2012).

[2] Arthritis Foundation, What is Rheumatoid Arthritis, http://www.arthritis.org/types-what-is-rheumatoid-arthritis.php (Accessed: May 1, 2012).

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)
(Logo: http://photos.prnewswire.com/prnh/20120608/DE21226LOGO)

SOURCE Eli Lilly and Company; Incyte Corporation