Lilly and Incyte Announce Patients Treated with Baricitinib Demonstrated Significant Improvement in Signs and Symptoms of Rheumatoid Arthritis Compared with Methotrexate

November 7, 2015

INDIANAPOLIS, Nov. 7, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announce detailed data from the pivotal phase 3 RA-BEGIN study, which show investigational baricitinib alone and in combination were superior to methotrexate monotherapy in helping patients achieve clinical remission. Findings will be shared at the American College of Rheumatology /Association of Rheumatology Health Professionals annual meeting in San Francisco, revealing superiority for investigational therapy baricitinib over methotrexate in improving multiple measures of the signs and symptoms of rheumatoid arthritis. --> INDIANAPOLIS, Nov. 7, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announce detailed data from the pivotal phase 3 RA-BEGIN study, which show investigational baricitinib alone and in combination were superior to methotrexate monotherapy in helping patients achieve clinical remission. Findings will be shared at the American College of Rheumatology /Association of Rheumatology Health Professionals annual meeting in San Francisco, revealing superiority for investigational therapy baricitinib over methotrexate in improving multiple measures of the signs and symptoms of rheumatoid arthritis. -->

- Compared to methotrexate, baricitinib as monotherapy or in combination with methotrexate demonstrated improvements in all ACR components as early as week 1 and maintained through 52 weeks

- Both baricitinib regimens were superior to methotrexate monotherapy in inducing clinical remission, using measures such as SDAI, at weeks 24 and 52

- Baricitinib plus methotrexate also demonstrated significant inhibition of progressive radiographic structural joint damage measured using van der Heijde modified Sharp Score versus methotrexate alone at weeks 24 and 52

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Lilly and Incyte previously announced that the study met its primary objective of demonstrating the non-inferiority of baricitinib monotherapy to methotrexate monotherapy based on ACR20 response rate after 24 weeks of treatment. Additionally, it was announced that baricitinib was superior to methotrexate based on ACR20 response.

Roy Fleischmann, M.D., lead study author and clinical professor of medicine at the University of Texas Southwestern Medical Center in Dallas. "If it gains FDA approval, baricitinib could be a new choice for us to turn to, especially for patients who cannot take methotrexate." --> Roy Fleischmann, M.D., lead study author and clinical professor of medicine at the University of Texas Southwestern Medical Center in Dallas. "If it gains FDA approval, baricitinib could be a new choice for us to turn to, especially for patients who cannot take methotrexate." -->

"Left untreated or uncontrolled, RA can progress and significantly impact long-term health, career and quality of life," said Roy Fleischmann, M.D., lead study author and clinical professor of medicine at the University of Texas Southwestern Medical Center in Dallas. "If it gains FDA approval, baricitinib could be a new choice for us to turn to, especially for patients who cannot take methotrexate."

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In the RA-BEGIN trial, 584 patients who had limited or no prior treatment with methotrexate and who had never received other conventional or biologic disease-modifying antirheumatic drugs (DMARDs) were randomized to methotrexate once weekly (n=210), baricitinib 4 mg once daily (n=159) or baricitinib daily in combination with methotrexate weekly (n=215) for up to 52 weeks. The weekly methotrexate dose was increased from 10 mg to 20 mg over 8 weeks.

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Improvements compared to methotrexate were seen for baricitinib alone or in combination with methotrexate as early as week 1 for all components of the ACR response (swollen and tender joint counts, pain, patient and physician global assessment of disease activity and physical function). These improvements were maintained at weeks 24 and 52.

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Baricitinib plus methotrexate also demonstrated significant inhibition of progressive radiographic joint damage versus methotrexate alone in RA-BEGIN, the third phase 3 study of baricitinib in RA to show this finding.

Terence Rooney, M.D., medical director, rheumatoid arthritis, Lilly Bio-Medicines. "These positive results for baricitinib add to the growing body of evidence supporting this balanced JAK1 and JAK2 inhibitor as a potential new once-daily oral treatment option for people living with active RA." --> Terence Rooney, M.D., medical director, rheumatoid arthritis, Lilly Bio-Medicines. "These positive results for baricitinib add to the growing body of evidence supporting this balanced JAK1 and JAK2 inhibitor as a potential new once-daily oral treatment option for people living with active RA." -->

"Reaching clinical remission as soon as possible is important to help prevent irreversible joint damage that could lead to disability," said Terence Rooney, M.D., medical director, rheumatoid arthritis, Lilly Bio-Medicines. "These positive results for baricitinib add to the growing body of evidence supporting this balanced JAK1 and JAK2 inhibitor as a potential new once-daily oral treatment option for people living with active RA."

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The incidence of treatment-emergent adverse events and serious adverse events, including serious infections, was similar across treatment groups through week 52. No cases of tuberculosis or spontaneous gastrointestinal perforation were reported during the study. The most common adverse events observed were consistent with previous studies of baricitinib in RA. Compared to methotrexate, baricitinib monotherapy was associated with lower rates of liver abnormalities, lymphopenia and adverse events leading to interruption, while the combination of baricitinib plus methotrexate was associated with increases in non-serious infections and adverse events leading to permanent discontinuation.

Rich Levy, M.D., chief drug development officer of Incyte. "We are very pleased with the results of the phase 3 RA-BEGIN study, which show superiority of baricitinib over methotrexate, a commonly used treatment for early RA, and demonstrate baricitinib's promise as a potential new treatment option that offers patients improved disease control." --> Rich Levy, M.D., chief drug development officer of Incyte. "We are very pleased with the results of the phase 3 RA-BEGIN study, which show superiority of baricitinib over methotrexate, a commonly used treatment for early RA, and demonstrate baricitinib's promise as a potential new treatment option that offers patients improved disease control." -->

"A significant medical need remains in the RA community as patients respond differently to different treatments," said Rich Levy, M.D., chief drug development officer of Incyte. "We are very pleased with the results of the phase 3 RA-BEGIN study, which show superiority of baricitinib over methotrexate, a commonly used treatment for early RA, and demonstrate baricitinib's promise as a potential new treatment option that offers patients improved disease control."

RA-BEACON, in February 2015 for the second, RA-BUILD, in September 2015 for the third, RA-BEGIN and in October 2015 for the fourth, RA-BEAM. The companies will also share detailed results from the RA-BEAM study at ACR this year and plan to submit additional detailed data from all four studies for presentation in scientific meetings and publication in peer-reviewed journals in 2016. --> RA-BEACON, in February 2015 for the second, RA-BUILD, in September 2015 for the third, RA-BEGIN and in October 2015 for the fourth, RA-BEAM. The companies will also share detailed results from the RA-BEAM study at ACR this year and plan to submit additional detailed data from all four studies for presentation in scientific meetings and publication in peer-reviewed journals in 2016. -->

Lilly and Incyte announced top-line results in December 2014 for the first phase 3 trial of baricitinib, RA-BEACON, in February 2015 for the second, RA-BUILD, in September 2015 for the third, RA-BEGIN and in October 2015 for the fourth, RA-BEAM. The companies will also share detailed results from the RA-BEAM study at ACR this year and plan to submit additional detailed data from all four studies for presentation in scientific meetings and publication in peer-reviewed journals in 2016.

About Baricitinib
Baricitinib is the only once-daily oral selective JAK1 and JAK2 inhibitor currently in late-stage clinical studies for inflammatory and autoimmune diseases. 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. --> About Baricitinib
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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, diabetic nephropathy and atopic dermatitis. --> 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

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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 Rheumatoid Arthritis

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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. 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 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 Baricitinib Phase 3 Trials

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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 20, 2015)

[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 20, 2015)

[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 October 20, 2015)

[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: October 20, 2015)

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