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Additional results from pivotal RA-BEAM study published in New England Journal of Medicine show baricitinib-treated patients demonstrated sustained improvement in rheumatoid arthritis compared to adalimumab and placebo

INDIANAPOLIS, Feb. 15, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today additional detailed results from RA-BEAM - a pivotal phase 3 study of baricitinib in the treatment of moderate-to-severe rheumatoid arthritis (RA) - were published in the *New England Journal of Medicine*.

The *New England Journal of Medicine* publication includes supplementary data, which show that starting as early as week 8, and sustained through week 52, a higher proportion of patients taking baricitinib achieved ACR50 and ACR70 response - composite scores that represent at least 50 percent and 70 percent improvement, respectively, in multiple components of RA disease activity - compared to adalimumab (Humira®*). These improvements were statistically significant compared to adalimumab at weeks 12, 20, 28, 32 and 40. At week 52, both ACR50 and ACR70 rates were higher in the baricitinib group compared to adalimumab, although only ACR 50 was statistically significant.

A significantly higher proportion of patients taking baricitinib had low disease activity, assessed by the 28-joint Disease Activity Score (using high-sensitivity C reactive protein [DAS28-CRP]), Simplified Disease Activity Index (SDAI) and Clinical Disease Activity Index (CDAI) scores, compared to adalimumab at weeks 12 and 52.

Lilly and Incyte previously announced positive topline results of RA-BEAM, stating that 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.

"This is an exciting time for rheumatology, with potential new treatments for rheumatoid arthritis on the horizon. The RA-BEAM study of baricitinib is the first phase 3 trial showing that a once-daily, oral treatment significantly improved clinical outcomes compared with a current standard of care, injectable adalimumab used with background methotrexate therapy," said Peter Taylor, M.A., Ph.D., F.R.C.P., study author and Norman Collisson chair of Musculoskeletal Sciences in the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences at the University of Oxford. "These data demonstrate that baricitinib could provide another treatment option for people with rheumatoid arthritis."

The 52-week RA-BEAM study included more than 1,300 patients with inadequate response to methotrexate, all of whom continued to receive methotrexate through the study period. Patients were randomized to placebo once daily (n=488), baricitinib 4 mg once daily (n=487) or adalimumab 40 mg biweekly (n=330). At week 24, patients taking placebo were crossed over to the baricitinib treatment group. The design of the head-to-head study and statistical analysis plan included prespecified and controlled for multiple testing for both non-inferiority and superiority of baricitinib compared with adalimumab.

Detailed safety results from the trial show that the percentage of patients stopping therapy due to adverse events through week 24 were 3 percent in placebo, 5 percent in baricitinib and 2 percent in the adalimumab group. Serious adverse event rates through 24 weeks were similar with placebo and baricitinib (5 percent each) and lower with adalimumab (2 percent).

Through the 52-week period, serious adverse event rates were 8 percent for baricitinib and 4 percent for adalimumab. Patients stopping therapy due to adverse events from baseline through week 52 were 7 percent for baricitinib and 4 percent for adalimumab. Major adverse cardiovascular events (MACE) were reported in less than 1 percent of patients in both the baricitinib and adalimumab groups (baseline through 52 weeks). A total of 5 deaths were reported in the study (1 placebo, 2 baricitinib, 1 adalimumab and 1 placebo rescued to baricitinib).

Baricitinib, an investigational medicine for the treatment of moderate-to-severe RA, is in the late stages of regulatory review in the United States and Japan. In February 2017, the European Commission granted marketing authorization for baricitinib for the treatment of moderate-to-severe RA in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs (DMARDs).

About Baricitinib
Baricitinib is a 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.

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 was submitted for regulatory review seeking marketing approval for the treatment of rheumatoid arthritis in the U.S., European Union and Japan in Q1 2016, and is being studied in phase 2 trials for atopic dermatitis and systemic lupus erythematosus.

About Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease characterized by inflammation and progressive destruction of joints.[i,ii] More than 23 million people worldwide suffer from RA.[iii] Approximately three times as many women as men have the disease. Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, oral conventional disease-modifying antirheumatic drugs (cDMARDs), such as methotrexate - the current standard of care - and injectable, biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.[iv] Despite current treatment options, many patients do not reach their therapeutic goals or sustained remission.[v,vi] There remains an important need to provide additional treatments to improve overall patient care.

About Baricitinib Phase 3 Trials

Lilly and Incyte 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 antirheumatic 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 additional information on Incyte, please visit the Company's web site at www.incyte.com.

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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.

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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 rheumatoid arthritis and the RA-BEAM trial, and reflects Lilly and Incyte's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be 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 most recent 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: September 15, 2016)

[ii] Hand Clinics, *Advances in the Medical Treatment of Rheumatoid Arthritis*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf (Accessed: September 15, 2016)

[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 September 15, 2016)

[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: September 15, 2016)

[v] Rheumatoid arthritis, *Lancet,* https://www.ncbi.nlm.nih.gov/pubmed/27156434 (Accessed: September 15, 2016)

[vi] Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/ (Accessed: September 15, 2016)

Refer to:

Scott MacGregor; jsmacgregor@lilly.com; +1-317-440-4699 (Lilly media)
Phil Johnson; johnson_philip_l@lilly.com; +1-317-655-6874 (Lilly investors)
Catalina Loveman; cloveman@incyte.com; +1-302-498-6171 (Incyte media)
Michael Booth, DPhil; mbooth@incyte.com; +1-302-498-5914 (Incyte investors)

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