November 5, 2017

ACR/ARHP 2017: New Analysis Shows Rheumatoid Arthritis Patients Treated with Baricitinib Reported Greater Improvements in Pain Compared to Adalimumab or Placebo

- Post-hoc analysis presented at ACR/ARHP shows pain improvement was consistent regardless of a patient's baseline pain severity

INDIANAPOLIS, Nov. 5, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that patients with moderate-to-severe rheumatoid arthritis (RA) treated with baricitinib reported greater improvements in pain control when compared to Humira®* (adalimumab) or placebo. A new post-hoc analysis of the Phase 3 RA-BEAM study disclosing outcomes of patient-reported levels of pain control will be presented today at the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Meeting in San Diego, Calif.

"While there are many treatments available for RA patients, these data suggest that baricitinib, if approved, may be an important advancement for patients suffering from RA-related pain," said James McGill, M.D., distinguished medical fellow and global brand development leader, Lilly Bio-Medicines. "We are pleased to share these data suggesting that baricitinib could provide a potential new option for people living with RA. We remain committed to making life better for people with rheumatoid arthritis and improving patient care."

RA-BEAM Post-hoc Analysis of Study Results

RA-BEAM was a 52-week trial of 1,305 patients who had active, moderate-to-severe RA, despite ongoing treatment with methotrexate. Patients were randomized to placebo once daily (n=488), baricitinib 4 mg once daily (n=487) or adalimumab 40 mg biweekly (n=330). All patients received background methotrexate. This post-hoc analysis reviewed outcomes of patient-reported levels of pain control during the first 24 weeks of the trial as measured by a 0-100 mm visual analog scale (VAS) during each study visit. Analyses were not adjusted for multiplicity, were exploratory in nature and further research should be conducted to confirm these results. Analysis of reduction in pain included an assessment of the time required to achieve ≥30 percent, ≥50 percent and ≥70 percent pain improvement, including the following results:

- Patients treated with baricitinib reported 30-percent pain improvement at a median 1.9 weeks post-baseline, compared to adalimumab at a median 2 weeks and placebo at a median 4.6 weeks.
- Patients treated with baricitinib reported 50-percent pain improvement at a median four weeks post-baseline, compared to adalimumab at a median 7.9 weeks and placebo at a median 14 weeks.
- Patients treated with baricitinib reported 70-percent pain improvement at a median 12.4 weeks post-baseline, compared to adalimumab at a median 20 weeks and placebo at a median of greater than 24 weeks. From Week 24, non-rescued patients in the placebo group were switched to receive baricitinib.

For patients whose baseline pain levels were higher than the median, treatment with baricitinib also led to faster pain improvements than adalimumab or placebo.

"Many RA patients continue to struggle with chronic pain," said Peter Taylor, M.A., Ph.D., presenting author and Professor at the University of Oxford. "These post-hoc analyses suggest that these RA patients may derive meaningful and consistent improvements in pain, particularly those patients with the highest pain at baseline."

The observed safety profile in RA-BEAM was consistent with previous trials evaluating baricitinib. 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). No additional safety signals were observed during the post-hoc analysis.

Lilly plans to resubmit the New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for baricitinib as a treatment for adult patients with RA before the end of January 2018. Baricitinib is approved for the treatment of adult patients with RA in several geographies, including the European Union and Japan.

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About Baricitinib
Baricitinib is a once-daily oral JAK inhibitor currently in 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, including rheumatoid arthritis.

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., the European Union and Japan in 2016. Baricitinib was approved in the EU in February 2017 and in Japan in July 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for baricitinib. Baricitinib remains under review in other markets. It is also being studied for the treatment of atopic dermatitis and systemic lupus erythematosus. The Phase 3 program for psoriatic arthritis is expected to begin in 2018.

About Rheumatoid Arthritis
Rheumatoid arthritis is a systemic autoimmune disease characterized by inflammation and progressive destruction of joints.[1,2] More than 23 million people worldwide suffer from RA.[3] 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 synthetic disease-modifying antirheumatic drugs (csDMARDs), such as methotrexate, and injectable, biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.[4] Despite current treatment options, many patients do not reach their therapeutic goals or sustained remission.[5,6] There remains an important need to provide additional treatments to improve overall patient care.

About Baricitinib Phase 3 Trials
Lilly and Incyte conducted four successful pivotal Phase 3 clinical trials of baricitinib in patients with moderate-to-severe active rheumatoid arthritis to support regulatory submission in most countries. Two of the four studies included pre-specified comparisons to approved DMARDs: one to methotrexate (RA-BEGIN) and one to adalimumab (RA-BEAM). An additional phase 3 study recently concluded 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 synthetic disease modifying antirheumatic drugs, or inadequate responders to bDMARDs including TNF inhibitors. Patients completing any of the Phase 3 studies were able to 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 patients with rheumatoid arthritis and reflects Lilly's and Incyte's current beliefs. 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 baricitinib will receive regulatory approval or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent respective Form 10-K and Form 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.

[1] American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp. Accessed November 1, 2017.

[2] Hand Clinics, Advances in the Medical Treatment of Rheumatoid Arthritis, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf. Accessed November 1, 2017.

[3] 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 November 1, 2017.

[4] 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 November 1, 2017.

[5] Rheumatoid arthritis, Lancet, https://www.ncbi.nlm.nih.gov/pubmed/27156434. Accessed November 1, 2017.

[6] Sustained rheumatoid arthritis remission is uncommon in clinical practice, Arthritis Research & Therapy, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/. Accessed November 1, 2017.

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