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Lilly and Incyte Announce Submission of New Drug Application to FDA for Oral Once-Daily Baricitinib for Treatment of Moderate-to-Severe Rheumatoid Arthritis

INDIANAPOLIS, Jan. 19, 2016 /PRNewswire/ --Â Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) today announced that Lilly has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for the approval of oral once-daily baricitinib for the treatment of moderately-to-severely active rheumatoid arthritis (RA).

As a result, Incyte will receive a milestone payment of $35 million from Lilly related to the NDA submission. If baricitinib is granted U.S. regulatory approval, Incyte will receive a milestone payment of $100 million from Lilly. Incyte could earn additional global regulatory as well as sales-based milestone payments and be eligible for royalties on global net sales of baricitinib.

If approved, Lilly will lead launch and global commercialization efforts for baricitinib in RA. Lilly owns global rights to develop and commercialize baricitinib as an oral treatment for all inflammatory conditions.

This submission milestone will result in a first-quarter charge to Lilly's GAAP and non-GAAP research and development expense of $35 million (pre-tax).Â Lilly's previously-issued 2016 GAAP and non-GAAP EPS guidance of $2.92-$3.02 and $3.45-$3.55, respectively, remain unchanged.

"Lilly's collaboration with Incyte has produced a rigorous phase 3 program and, if approved, the potential of a promising new treatment option for people with RA," said David Ricks, president of Lilly Bio-Medicines.

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.

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, diabetic nephropathy, atopic dermatitis and systemic lupus erythematosus.

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 completed 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 DMARD naïve, inadequate responders to methotrexate, inadequate responders to conventional disease-modifying anti-rheumatic drugs, or inadequate responders to biologic DMARDs. 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 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
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. **P-LLY**

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] Â American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.aspÂ (Accessed:Â October 20, 2015)

[ii] Â Hand Clinics,Â *Advances in the Medical Treatment of Rheumatoid Arthritis*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdfÂ (Accessed:Â October 20, 2015)

[iii] Â WHOÂ Global Burden of Disease Report, (table 7, page 32) 2004, http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdfÂ (AccessedÂ October 20, 2015)

[iv] Â Arthritis Foundation, Medications for Rheumatoid Arthritis,Â http://www.arthritistoday.org/about-arthritis/types-of-arthritis/rheumatoid-arthritis/treatment-plan/medication-overview/ra-medications.phpÂ (Accessed:Â October 20, 2015)

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