CHMP Recommends Approval of Lilly's Baricitinib for the Treatment of Adults with Moderate to Severe Active Rheumatoid Arthritis (RA)

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INDIANAPOLIS, Dec. 16, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion, recommending the approval of baricitinib - which if approved would be marketed as Olumiant®. Baricitinib would be indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate.

This is the first regulatory step towards the approval of baricitinib and the CHMP positive opinion is now referred for final action to the European Commission, which grants approval in the EU. The Commission usually makes a decision on marketing authorization within two to three months of the CHMP issuing its recommendation.

"Rheumatoid arthritis is a debilitating disease and can have a devastating impact on a person's quality of life," said Andrew Hotchkiss, president of Lilly's European and Canadian operations. "There is no cure for rheumatoid arthritis and although improvements have been seen in the long term outcomes for patients, not all people reach low disease activity or remission. Baricitinib is the first JAK inhibitor to receive a positive CHMP opinion for the treatment of RA in the EU. It is an important milestone for people living with rheumatoid arthritis and Lilly is committed to improving outcomes for people living with this chronic condition."

The CHMP positive opinion was based on five phase 3 clinical trials of baricitinib in adult patients with moderate to severe active rheumatoid arthritis (RA-BEGIN, RA-BEAM, RA-BUILD, RA-BEACON and RA-BEYOND). A wide range of patients participated in the clinical trial program, including those who are inadequate responders to methotrexate, inadequate responders to conventional synthetic disease modifying anti rheumatic drugs (csDMARDs), or inadequate responders to biological disease modifying anti rheumatic drugs (bDMARDs) including TNF inhibitors.

"The positive opinion for baricitinib paves the way for adults with rheumatoid arthritis to be offered a new treatment option," said Steven Stein, M.D., chief medical officer, Incyte Corporation. "Incyte is proud to have partnered with Lilly on the research and development of this promising medicine, and we are pleased that the CHMP positive opinion brings us one step closer to providing baricitinib to the many people living with this chronic condition."

The $65 million milestone payment that was to be paid by Lilly to Incyte upon positive CHMP opinion will now be triggered by the granting of marketing authorization by the EU Commission per a recent amendment to the parties' Agreement.

About Baricitinib

Baricitinib is a once-daily oral, selective and reversible JAK1 and JAK2 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.

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 a systemic 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 synthetic disease-modifying antirheumatic drugs (csDMARDs), 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 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 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 synthetic disease modifying antirheumatic drugs, or inadequate responders to biologic DMARDs including 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 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 www.lilly.com/newsroom/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 future study results will be consistent with the results to date or that baricitinib will achieve its primary study endpoints or receive regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent 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.

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i American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp. Accessed Dec 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 Dec 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 Dec 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 Dec 15, 2016.
v Rheumatoid arthritis, *Lancet,* https://www.ncbi.nlm.nih.gov/pubmed/27156434. Accessed Dec 015, 2016.
vi Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/. Accessed Dec 15, 2016.

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