Lilly to File Baricitinib Resubmission to U.S. FDA before end of January 2018

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INDIANAPOLIS , Aug. 30, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE : LLY) and Incyte Corporation (NASDAQ: INCY) announced today that, after discussions with the U.S. Food and Drug Administration (FDA) in late August, Lilly will resubmit the New Drug Application (NDA) for baricitinib before the end of January 2018 . The resubmission package will include new safety and efficacy data. The companies anticipate the FDA will classify the application as a Class II resubmission, which will start a new six-month review cycle. Baricitinib is a once-daily oral investigational medication for the treatment of patients with moderate-to-severe rheumatoid arthritis (RA).

"We are committed to making life better for people living with RA. There is a significant unmet need for Americans suffering from this debilitating disease in spite of available therapies," said Christi Shaw, president of Lilly Bio-Medicines. "We are pleased with the opportunity to provide our resubmission package for baricitinib sooner than anticipated and look forward to continuing to work with the FDA as we seek to bring baricitinib to people with RA in the U.S. "

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.[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 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.

[i] American College of Rheumatology, Rheumatoid Arthritis, http://www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/ra.asp. Accessed July 21, 2017 .

[ii] Hand Clinics, *Advances in the Medical Treatment of Rheumatoid Arthritis*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135413/pdf/nihms305780.pdf. Accessed July 21, 2017 .

[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 July 21, 2017 .

[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 July 21, 2017 .

[v] Rheumatoid arthritis, *Lancet ,* https://www.ncbi.nlm.nih.gov/pubmed/27156434. Accessed July 21, 2017 .

[vi] Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/. Accessed July 21, 2017 .