U.S. FDA Extends Review Period for Baricitinib, an Investigational Rheumatoid Arthritis Treatment

January 13, 2017

INDIANAPOLIS, Jan. 13, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that the U.S. Food and Drug Administration (FDA) has extended the review period for the new drug application (NDA) for investigational baricitinib, a once-daily oral medication for the treatment of moderate to severe rheumatoid arthritis (RA). The NDA for baricitinib was submitted to the FDA in January 2016.

The FDA extended the action date to allow time to review additional data analyses recently submitted by Lilly in response to the FDA's Information Requests. The submission of the additional information has been determined by the FDA to constitute a Major Amendment to the NDA, resulting in an extension of the Prescription Drug User Fee Act (PDUFA) goal date by three months.

"At Lilly, we are committed to improving the lives of people with life-long chronic diseases such as rheumatoid arthritis, a serious and disabling type of arthritis," said J. Anthony Ware, M.D., senior vice president, product development and interim president of Lilly Bio-Medicines. "We will continue to work closely with the FDA throughout the review process and we believe that baricitinib has the potential to be an effective treatment choice, especially for those patients for whom current therapies are not adequately addressing their disease."

This delay does not affect Lilly's previously-issued financial guidance for 2017.

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.

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. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion in December 2016, recommending the approval of baricitinib - which if approved would be marketed as Olumiant®. Baricitinib is also being studied in phase 2 trials for atopic dermatitis and systemic lupus erythematosus, and a phase 3 trial for patients with psoriatic arthritis is expected to be initiated in 2017.

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.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

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'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 achieve its primary study endpoints or receive additional regulatory approvals. 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 December 5, 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 December 5, 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. Acce Accessed December 5, 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 December 5, 2016.

[v] Rheumatoid arthritis, *Lancet,* https://www.ncbi.nlm.nih.gov/pubmed/27156434. Accessed December 5, 2016.

[vi] Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/. Accessed December 5, 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)

SOURCE Eli Lilly and Company