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European Commission Approves Once-Daily Olumiant Tablets for Treatment of Adults with Moderate-to-Severe Active Rheumatoid Arthritis

Baricitinib, marketed as Olumiant, is the first JAK inhibitor approved to treat RA in the EU

INDIANAPOLIS, Feb. 13, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that the European Commission has granted marketing authorisation for Olumiant® (baricitinib) 4 mg and 2 mg film-coated tablets in Europe for the treatment of moderate-to-severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs).

This is the first regulatory approval around the world for Olumiant -- the first JAK inhibitor approved to treat RA in the European Union -- which may be used as monotherapy or in combination with methotrexate. In clinical studies, Olumiant has demonstrated significant improvement in the signs and symptoms of RA compared to standard of care therapies such as methotrexate and Humira®* (adalimumab) with background methotrexate.

"Despite clinical advances in treatment, many people with RA continue to struggle with the debilitating effects of this disease, which can lead to long-term joint damage and disability," said J. Anthony Ware, M.D., senior vice president for product development and interim president, Lilly Bio-Medicines. "We believe that as a next-generation therapy in the EU, Olumiant will advance RA treatment by helping patients with moderate-to-severe disease feel better quickly."

Baricitinib's phase 3 program includes four completed clinical studies in a wide range of adult patients with RA, from treatment-naïve patients to those who are inadequate responders to TNF inhibitors. Two of those studies, RA-BEGIN and RA-BEAM, included a pre-specified comparison against either methotrexate or Humira with background methotrexate. Patients completing any of the phase 3 studies could enroll in a long-term extension study.

"The European Commission's approval of baricitinib is an exciting milestone for the RA community in the EU," said Steven Stein, M.D., chief medical officer, Incyte Corporation. "We're confident that baricitinib will help to meet the needs of healthcare providers and their patients as they work toward achieving long-term treatment goals."

As a result of the approval of Olumiant by the European Commission, Incyte becomes eligible to receive a milestone payment of $65 million from Lilly, which it expects to record in full in the first quarter of 2017.

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, 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., European Union and Japan in 2016. It is 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.

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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 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, receive additional regulatory approvals, 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 January 9, 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 January 9, 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 January 9, 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 January 9, 2017.

[v] Rheumatoid arthritis, *Lancet,* https://www.ncbi.nlm.nih.gov/pubmed/27156434. Accessed January 9, 2017.

[vi] Sustained rheumatoid arthritis remission is uncommon in clinical practice, *Arthritis Research & Therapy*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3446437/. Accessed January 9, 2017.

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