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Japan Ministry of Health, Labor and Welfare (MHLW) Grants Marketing Approval For Olumiant® (baricitinib) for the Treatment of Rheumatoid Arthritis

INDIANAPOLIS, July 3, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that Japan's Ministry of Health, Labor and Welfare (MHLW) granted marketing approval for Olumiant® (baricitinib) 2-mg and 4-mg tablets for the treatment of rheumatoid arthritis (RA) (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies.

The Olumiant approval is based on the results of the baricitinib development program, which includes four phase 3 clinical trials enrolling various populations of more than 3,000 moderate-to-severe RA patients worldwide, including more than 500 Japanese patients. In clinical studies, baricitinib has demonstrated significant improvement in the signs and symptoms of RA compared to standard-of-care therapies.

Despite clinical advances in the treatment of RA, some people do not achieve optimal control of their disease or they discontinue treatment due to lack of efficacy or side effects, which can lead to long-term damage and disability. In Japan, an estimated 700,000-800,000 people suffer from RA, and women are three times more likely to be affected than men.[i,ii]

"Today is an important milestone for the RA community in Japan. Olumiant has been shown to provide effective relief of RA symptoms in people who do not respond to standard treatments, as well as prevent the structural damage to joints that makes RA a progressive, debilitating disease," said Christi Shaw, president of Lilly Bio-Medicines.

"The phase 3 clinical trial program of Olumiant consistently showed significant improvement in clinical signs and symptoms of RA in a wide range of RA patients with a diverse treatment history," said Steven Stein, M.D., chief medical officer, Incyte Corporation. "We are pleased to have helped develop this new treatment option for the RA community in Japan."

The Japan marketing authorization of Olumiant triggers a $15 million milestone payment from Lilly to Incyte, which Incyte expects to recognize, in full, in the third quarter of 2017.

About Olumiant

Olumiant® (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., European Union and Japan in 2016. Olumiant was approved in the EU in February 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for Olumiant. Olumiant was also approved in Kuwait and Switzerland in June 2017 and approved in Japan in July 2017 for the treatment of RA.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an autoimmune disease characterized by inflammation and progressive destruction of joints. More than 23 million people worldwide suffer from RA.[iii] Approximately three times as many women as men have the disease.[ii] Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs (NSAIDs), oral conventional disease-modifying antirheumatic drugs (cDMARDs) - such as methotrexate, the current standard of care, and injectable and intravenous 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 are not able to achieve sustained remission.[v] There remains an important need to provide additional treatment options to improve overall patient care.

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.

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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(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 belief. 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, that baricitinib will 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 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] Report from Study Committee on Rheumatoid Arthritis and Allergy http://www.mhlw.go.jp/stf/houdou/2r9852000001nfao-att/2r9852000001nfdx.pdf (Accessed on June 13, 2017)

[ii] Arthritis Foundation, What is Rheumatoid Arthritis?, http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoid-arthritis.php (Accessed: May, 16, 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: May, 16, 2017)

[iv] Arthritis Foundation, Rheumatoid Arthritis Treatment, http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/treatment.php (Accessed: May, 16, 2017)

[v] McWilliams DF, Kiely PDW, Young A, Walsh DA. Baseline factors predicting change from the initial DMARD treatment during the first 2 years of rheumatoid arthritis: experience in the ERAN inception cohort. BMC Musculoskeletal Disorders. 2013;14:1-7.

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