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Pfizer Provides Update on Global Regulatory Approvals and Launches of XELJANZ® (tofacitinib citrate) for the Treatment of Rheumatoid Arthritis

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NEW YORK, N.Y., July 15 - Pfizer Inc. (NYSE: PFE) announced today that tofacitinib has been approved for the treatment of rheumatoid arthritis (RA) in patients who had an inadequate response to existing therapies in several additional countries around the world, including Switzerland, which is the first European country to receive approval. Swissmedic, the Swiss agency for therapeutic products, approved tofacitinib 5 and 10 mg twice-daily (BID) as monotherapy or in combination with a disease modifying non-biologic antirheumatic agent (DMARD), including methotrexate (MTX), in adult patients with moderate-to-severe active RA who have had an inadequate response or intolerance to MTX. Tofacitinib 5 mg BID has also been approved in Argentina, Kuwait and the United Arab Emirates, and tofacitinib 5 mg and 10 mg BID has been approved in Russia. The brand name for tofacitinib in the approved markets will be XELJANZ, except for Russia, where the brand name will be Jaquinus®.

As previously announced, XELJANZ 5 mg BID is also approved in the United States and Japan for the treatment of moderate-to-severe active RA. XELJANZ was launched in the United States in November 2012, and XELJANZ is expected to be commercially available in Japan this month following approval by the Japanese Ministry of Health, Labor and Welfare (MHLW) in March 2013. XELJANZ will be co-promoted in Japan by Pfizer and Takeda Pharmaceutical Company Limited. Initially, XELJANZ will be made available in Japan to medical institutions participating in an all-patient surveillance program, designed by Pfizer in collaboration with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and the Japan College of Rheumatology.

"More than 23 million people worldwide are living with rheumatoid arthritis and there remains an unmet need for additional treatments, with up to one-third of RA patients not adequately responding and about half who stop responding to any particular DMARD within five years," said Geno Germano, president and general manager, Specialty Care and Oncology, Pfizer. "XELJANZ has a novel mechanism of action for the treatment of moderate-to-severe RA. With these approvals, we believe XELJANZ has the potential to change the way rheumatologists treat this chronic, and potentially disabling, disease, and we are proud to offer patients and physicians an additional treatment option."

Regulatory applications for XELJANZ for the treatment of moderate-to-severe active RA remain under review in more than 30 additional countries. In Europe, Pfizer is seeking a re-examination of the Committee for Medicinal Products for Human Use (CHMP) negative opinion that was announced in April, and the company is currently working with the CHMP on the next steps in the process.

XELJANZ is the first approved RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors. The recent marketing authorizations for XELJANZ were based on data from the comprehensive, global, multi-study clinical development program for XELJANZ, which included approximately 5,000 patients in more than 40 countries, resulting in 7,000 patient-years of experience at the time of regulatory submission.

Important Safety Findings for XELJANZ

Notable safety findings observed in the XELJANZ RA program include serious and other important infections, including tuberculosis and herpes zoster; malignancies, including lymphoma; gastrointestinal perforations; decreased neutrophil and lymphocyte counts; and lipid elevations. The most common serious adverse events were serious infections. The most commonly reported adverse events were upper respiratory tract infections, headache, nasopharyngitis and diarrhea.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory autoimmune disease that typically affects the hands and feet, although any joint lined by a synovial membrane may be affected. RA can be painful and disabling,[1] causing swelling, stiffness and loss of function in the joints.[1] RA affects 23.7 million people worldwide,[2] and although multiple treatments are available, up to one-third of patients do not adequately respond, and about half stop responding to any particular DMARD within five years.[3],[4],[5],[6],[7],[8] As a result, there remains a need for additional options.

About XELJANZ

XELJANZ is a novel, oral Janus kinase (JAK) inhibitor for the treatment of RA. Unlike recent therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, XELJANZ takes a novel approach targeting the intracellular pathways that operate as hubs in the inflammatory cytokine network.

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This release contains forward-looking information about XELJANZ (tofacitinib citrate), including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, whether we will be able to address the CHMP's concerns to its satisfaction regarding the Marketing Authorization Application for XELJANZ for the treatment of adults with moderate-to-severe rheumatoid arthritis (the proposed indication) and receive a positive opinion from the CHMP for the proposed indication; whether and when the European Commission and regulatory authorities in other jurisdictions will approve applications that have been or may be submitted for the proposed indication, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; uncertainties regarding the commercial success of the proposed indication; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012, and in its reports on Form 10-Q and Form 8-K.

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Media Contact: Kim Bencker 610.329.1340 (m) Kim.Bencker@pfizer.com Investor Contact: Suzanne Harnett 212.733.8009 (o) Suzanne.Harnett@pfizer.com