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XELJANZ® (tofacitinib citrate) Approved in Japan for the Treatment of Adults with Rheumatoid Arthritis (RA)

Sunday, March 24, 2013 - 09:50pm

"RA is a serious and disabling disease and there is a need for new treatment options, as a significant number of patients do not adequately respond to current therapies,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved XELJANZ® (tofacitinib citrate) for the treatment of adults with rheumatoid arthritis (RA) who have had an inadequate response to existing therapies. XELJANZ may be used in patients in whom clinical symptoms due to the disease remain even after appropriate treatment with at least one other disease-modifying antirheumatic drug (DMARD), such as methotrexate. The recommended dose of XELJANZ is 5 mg twice daily.

XELJANZ will be commercially available in Japan after the National Health Insurance listing and will be co-promoted in Japan by Pfizer and Takeda Pharmaceutical Company Limited. Pfizer and Takeda also currently co-promote the RA drug Enbrel® (etanercept) in Japan.

XELJANZ (ZEL' JANZ') is the first approved oral treatment in a new class of medicines known as Janus kinase (JAK) inhibitors. Initially, XELJANZ will be made available in Japan to medical institutions participating in an all-patient surveillance program.

"RA is a serious and disabling disease and there is a need for new treatment options, as a significant number of patients do not adequately respond to current therapies," said Mark Swindell, Head of Pfizer Specialty Care Business Unit in Japan. "We are proud of our strong portfolio of treatments for inflammatory disorders in Japan, and we are pleased with the approval of XELJANZ, which allows us to offer an additional treatment option for RA patients."

Unlike biologic therapies that target RA outside the cell, XELJANZ targets the disease from inside the cell. It is specifically designed to inhibit the Janus kinase (JAK) pathways, which are signalling pathways inside the cell that play a role in the inflammation involved in RA.

The approval of XELJANZ in Japan is supported by a multi-study, global clinical development program, which evaluated XELJANZ in approximately 5,000 patients across various RA patient populations. The application also included data from Japanese subjects from two phase 2 studies, one phase 3 study and an ongoing long-term extension study. Across five global pivotal trials, XELJANZ 5 mg twice daily demonstrated efficacy, whether administered alone or in combination with a non-biologic DMARD, such as methotrexate, in patients who had a previous inadequate response to non-biologic or biologic DMARDs, including tumor necrosis factor (TNF) inhibitors.

XELJANZ is approved for the treatment of RA patients who have had an inadequate response to existing therapies. 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 affects approximately 700,000 – 800,000 people in Japan[1] and 23.7 million people worldwide.[2] Although multiple treatments are available, many patients do not adequately respond. Specifically, 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] There remains a need for additional options.

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[1] Report from Study Committee on Rheumatoid Arthritis and Allergy Accessed on 13 March 2013. http://www.mhlw.go.jp/stf/houdou/2r9852000001nfao-att/2r9852000001nfdx.pdf

[2] World Health Organization, “The Global Burden of Disease, 2004 Update.” Accessed 13 March 2012. Available at http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf.

[3] Klareskog L, Van der Heijde D, de Jager J, et al. Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomized controlled trial. *The Lancet* 2004. 363: 675-681

[4] Keystone, E, Kavanaugh A, Sharp J, et al. Radiographic, clinical and functional outcomes of treatment with adalimumab (a human anti-tumor necrosis factor monoclonal antibody) in patients with active rheumatoid arthritis receiving concomitant methotrexate therapy. *Arthritis & Rheumatism* 2004. 50: 1400-1411

[5] Lipsky, P, Van der Heijde, D, St. Clair, W. Infliximab and methotrexate in the treatment of rheumatoid arthritis. *The New England Journal of Medicine* 2000. 1594-1602.

[6] Duclos M, Gossec L, Ruyssen-Witrand A, et al. Retention rates of tumor necrosis factor blockers in daily practice in 770 rheumatic patients. J Rheumatol 2006; 33:2433-8.

[7] Maradit-Kremers H, Nicola PJ, Crowson CS, et al. Patient, disease, and therapy-related factors that influence discontinuation of disease-modifying antirheumatic drugs: a population-based incidence cohort of patients with rheumatoid arthritis. J Rheumatol 2006; 33(2):248-55.

[8] Blum MA, Koo D, Doshi JA. Measurement and rates of persistence with and adherence to biologics for rheumatoid arthritis: a systematic review. Clin Ther 2011;33(7):901-913.

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