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Japan nods Pfizer arthritis drug Xeljanz

March 28, 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Pfizer's Xeljanz (tofacitinib citrate) has received approval for the treatment of adults with rheumatoid arthritis (RA) by the Japanese Ministry of Health, Labor and Welfare (MHLW). The recommended dose of Xeljanz is 5 mg twice daily.

The drug is indicated for use on 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. Xeljanz is the first approved oral treatment in a new class of medicines known as Janus kinase (JAK) inhibitors, which are signalling pathways inside the cell that play a role in the inflammation involved in rheumatoid arthritis (RA). Xeljanz will be commercially available in Japan after the National Health Insurance listing and will be co-promoted in Japan by Pfizer and Takeda Pharma.

Mr Mark Swindell, head, specialty care business unit, Pfizer, Japan, said that, "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. 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."

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 II studies, one phase III 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.