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Novel oral RA treatment Xeljanz launched in Japan

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Singapore: Pfizer Japan and Takeda Pharmaceutical have launched Xeljanz (tofacitinib citrate) in Japan. The medicine was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) in March for the treatment of adults with rheumatoid arthritis (RA) who have had an inadequate response to existing therapies.

Xeljanz is the first approved oral RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitor in Japan. Unlike biologic therapies that target cytokine outside the cell, the medicine targets the JAK pathways, which are signaling pathways inside the cell that play a role in the inflammation involved in RA.

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 approved dose of Xeljanz is 5 mg twice daily.

In order to ensure that Xeljanz is used safely and effectively, Pfizer and Takeda, with the cooperation of the Japan College of Rheumatology, are working to promote proper use of the product through the implementation of all cases surveillance in accordance with the college's 'Guidelines for Using Tofacitinib in All Cases Surveillance.' In the guidelines, Xeljanz is recommended for patients whose RA cannot be controlled even after more than three months of continuous treatment with over 8mg per week of methotrexate. Through the all cases surveillance, 4,000 patients with Xeljanz over an observation period of three years, additional information on Xeljanz's safety and efficacy is being collected and analyzed. Another group consisting of 2,000 patients starting RA medical treatment, but not with Xeljanz, is included in the surveillance so that a comparative study measuring the occurrence of malignant tumors and serious infections can be carried out.

"Rheumatoid arthritis is a serious disease causing physical impediments. Some patients cannot achieve adequate results with existing treatments and I have high hopes that the emergence of this new, highly convenient product will lead to better patient quality-of-life," said Professor Yoshiya Tanaka, First Department of Internal Medicine, University of Occupational and Environmental Health, Japan.

"Xeljanz, which has a new mechanism of action, has been recognized for its safety and efficacy through domestic clinical trials, but it is important to promote the proper use of the medicine and to continue accumulating clinical evidence from the

field," Professor Tanaka added.