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Japan approves Crimzia for arthritis patients

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Singapore: UCB Japan received marketing approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for Cimzia (certolizumab pegol).

Cimzia, which is under joint-development by Astellas Pharma and UCB in Japan, has been approved as a 200 mg syringe for subcutaneous injection for the treatment of adult patients with rheumatoid arthritis (RA), who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage).

Cimzia is the only PEGylated Fc-free anti-TNF. In the Japanese clinical trials, improvements in the signs and symptoms of rheumatoid arthritis were observed in adult patients one week after administration of certolizumab pegol with or without methotrexate (MTX), in accordance with the criteria of the American College of Rheumatology.

Improvements were also observed in physical function as measured by the Health Assessment Questionnaire Disability Index (HAQ-DI) criteria. The progression of joint damage, as measured by change in Van der Heijde modified Total Sharpe Score (mTSS), was inhibited by certolizumab pegol when given with and without MTX. The safety profile of certolizumab pegol in the Japanese clinical trials was consistent with the safety profile reported in previous studies of certolizumab pegol in rheumatoid arthritis.

Certolizumab pegol is designed in the form of a prefilled syringe to facilitate self-administration by RA patients, once trained by their healthcare professional.