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Astellas, UCB announce approval of Cimzia in Japan

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Singapore:Ã?Â Astellas Pharma and UCB announced that UCB Japan has received marketing approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for Cimzia (INN;certolizumab pegol). Cimzia, under joint development in Japan, has been approved as a 200 mg syringe for subcutaneous (s.c) 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 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. For adult patients 400 mg s.c. should be administered at Weeks 0, 2, and 4, followed by 200 mg every 2 weeks. For maintenance dosing, 400mg every 4 weeks s.c. can be considered.

Certolizumab pegol is currently commercialized in over 30 countries in such regions as Europe and the United States. In January 2012 Astellas and UCB entered into the agreement to jointly develop and commercialize certolizumab pegol for rheumatoid arthritis in Japan. Under the terms of this agreement UCB will manufacture and supply the product for commercialization and Astellas will exclusively manage distribution and sales. In January 2012, UCB Japan filed an application for marketing approval for certolizumab pegol in Japan. Astellas will make a payment to UCB for the marketing authorization milestone which has already been included in the full-year business forecasts for the current fiscal year (ending March 2013 for Astellas).

Astellas and UCB believe that by launching certolizumab pegol in the Japanese market they will be able to provide RA patients with a new treatment option and contribute further to treatment of the disease.