

Astellas, UCB launch Cimzia in Japan

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Singapore: Astellas Pharma and UCB Japan have launched Cimzia (certolizumab pegol) in Japan for 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 and has a high affinity for TNF-alpha, a factor involved in the onset and exacerbation of inflammatory diseases, such as RA, and selectively inhibits the effects of TNF-alpha.

In Japanese clinical trials, improvements in the signs and symptoms of RA were observed in adult patients one week after administration of Cimzia 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 Cimzia when given with and without MTX.

The safety profile of Cimzia in the Japanese clinical trials was consistent with the safety profile reported in previous studies of Cimzia in RA conducted outside Japan.

Cimzia is 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 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.

Cimzia is currently commercialized in over 30 countries in such regions as Europe and the US. In January 2012, Astellas and UCB entered into the agreement to jointly develop and commercialize Cimzia for RA in Japan. Cimzia was granted Japanese marketing approval in December, 2012 and listed on the NHI price listing in February, 2013. Astellas will make a payment to UCB for the launch milestone. The impact of this milestone on Astellas' financial results of the current fiscal year, ending

March 31, 2013 will be immaterial.

Under the terms of the agreement, UCB will manufacture and supply the product for commercialization and Astellas will exclusively manage distribution and sales. Astellas and UCB Japan will work together to conduct promotion activities of the product in Japan.

Astellas and UCB Japan believe that by launching Cimzia 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.