



Astellas and UCB Launch Cimzia[®] (certolizumab pegol) in Japan for the treatment of adult patients with rheumatoid arthritis

Tokyo, Japan, 7 March, 2013 – [Astellas Pharma Inc.](#) (“Astellas”; Tokyo: 4503; President and CEO: Yoshihiko Hatanaka) and UCB Japan (“UCB Japan”: Tokyo, Japan, President and Representative Director: Joel Peterson)(solely “UCB” refers to the whole UCB group) announced the launch of Cimzia[®] (INN; certolizumab pegol) in Japan on March 8, 2013 for the indication of adult patients with rheumatoid arthritis (RA) who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage).¹

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.^{2,3} Improvements were also observed in physical function as measured by the Health Assessment Questionnaire Disability Index (HAQ-DI) criteria.^{2,3} 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.^{2,3} 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.⁴

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 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.¹

Cimzia[®] is currently commercialized in over 30 countries in such regions as Europe and the United States.⁵

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.

Product Summary

Product name:	Cimzia® 200 mg Syringe for S.C. Injection
Generic name:	Certolizumab Pegol
Indication:	Treatment of rheumatoid arthritis not responding to conventional therapy (including inhibition of progression of bone structural damage)
Dosage regimen:	Usually, for adult patients, Certolizumab pegol should be administered subcutaneously at 400 mg 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.
Package:	Cimzia® 200 mg Syringe for S.C. Injection: 1 Syringe
Drug Price:	Cimzia® 200 mg Syringe for S.C. Injection: ¥71,297
Drug price listing date:	22 February, 2013
Launch date:	8 March, 2013 (Plan)

Image of Package



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About RA

RA is a progressive disease which causes chronic inflammation of the joints.⁶ It generally affects joints in the body such as hands, wrists, feet and ankles, however the systemic nature of the condition means that it can also affect the body as a whole, including internal organs and the vascular system.^{6,7} It is estimated that 0.65 million people live with RA in Japan and over 23 million globally.^{8,9} Prevalence is not split evenly between genders, since women are three times more likely to be affected than men.⁷ Although RA can affect people of all ages, the onset of the disease usually occurs between 40-60 years of age.⁷

References

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For further information Astellas Pharma Inc.

Corporate Communications, Astellas Pharma Inc.

Tel: +81-3-3244-3201

Fax: +81-3-5201-7473

<http://www.astellas.com/en/>

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and Diabetes DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company Website at www.astellas.com/en.

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With about 9 000 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2012. UCB is listed on Euronext Brussels (symbol: UCB).