

The Results of Japanese Clinical Trials of Anti-TNF-alpha Antibody Certolizumab Pegol were Announced at Leading Rheumatology Meeting 2015 in Japan

Tokyo, Japan, 23 April, 2015-The additional analyses of C-OPERA, and long-term safety and efficacy over 4 years in J-RAPID and HIKARI studies were reported at the Annual General Assembly and Scientific Meeting of the Japan College of Rheumatology, April 23–25, 2015 in Nagoya, Japan. Certolizumab pegol (generic name) is the only Fc-free, PEGylated*¹ anti-TNF (Tumor Necrosis Factor)-alpha antibody (brand name in Japan: Cimzia[®] 200mg Syringe for S.C. Injection and brand name in Europe and US: Cimzia[®]). Cimzia[®] is being jointly developed and commercialized by Astellas Pharma Inc. (Tokyo:4503, "Astellas") and UCB Japan Co., Ltd. ("UCB Japan" and solely "UCB" refers to the whole UCB group) .

C-OPERA, the Japanese PIII clinical trials of certolizumab pegol (CZP), was designed to include methotrexate (MTX)-naïve early rheumatoid arthritis (RA) patients with poor prognostic factors, and to examine the efficacy and safety of one year treatment by CZP concomitant with MTX as compared to the treatment by MTX alone. The primary results of the study were reported at The European League Against Rheumatism 2014 and American College of Rheumatology (ACR) 2014 Annual Meeting.

In C-OPERA study, co-administration of CZP and MTX showed rapid amelioration of signs and symptoms of RA compared to MTX alone. This beneficial effect was clearly observed one week after the starting of administration, and sustained throughout the whole study period of 52 weeks. CZP+MTX also showed tendency of improvement of impaired job status and house work.

J-RAPID study, conducted in RA patients with inadequate response to MTX, and HIKARI study which had been conducted in RA patients who are not suitable for treatments with MTX, had both been performed with the aim of testing the safety and efficacy over long-term treatment of up to over 4 years until marketing. 66.3% of J-RAPID participants and 57.7% of HIKARI participants made it through, by Kaplan-Meier method*², to the 208th week of the studies, resulting in over 50% of persistency rate in both studies. No additional safety concerns have been observed regarding the long-term treatment.

Cimzia[®] is the world's first PEGylated anti-TNF-alpha (tumor necrosis factor alpha) antibody for the treatment of RA. It has a high affinity for TNF-alpha, which is involved in the onset and exacerbation of inflammatory diseases such as RA, and selectively inhibits the effects of TNF-alpha. It has an extended blood half-life due to PEG moiety attached to its Fc-free Fab region*³, and is effective in the treatment of RA as a subcutaneous injection either every two weeks or once a month. In clinical trials conducted in Japan, Cimzia[®] showed rapid and sustained reduction in signs and symptoms and prevented progression of joint destruction when administered with or without MTX. In global clinical trials, co-therapy with Cimzia[®] and MTX rapidly improved signs and symptoms of RA and continued to be effective during induction and maintenance therapy. Furthermore, Cimzia[®] prevented progression of joint bone destruction. Cimzia[®] is supplied in the form of a prefilled syringe to facilitate self-administration by RA patients trained by their healthcare professionals.

In January 2012, Astellas and UCB signed an agreement to jointly develop and commercialize Cimzia® in Japan. Cimzia® was granted Japanese marketing approval in December, 2012 and was launched in March, 2013. An application for the additional indication was filed in June, 2014 in Japan based on the findings obtained in the PIII C-OPERA clinical trial.

- *1: PEGylated – PEGylation refers to the modification of an antibody with polyethylene glycol.
- *2: Method to estimate survival curve.
- *3: The antibody is a Y-shaped molecule comprised of two antigen-recognizing Fab regions in the upper part and a complement-binding Fc region at the base.

About RA

RA is a progressive disease which causes chronic inflammation of the joints. It generally affects the smaller 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 vasculature. It is estimated that around 0.65 million people in Japan and 5 million people worldwide live with RA. Women are three times more likely to be affected than men. Although RA can affect people of all ages, the onset of the disease usually occurs between the ages of 40 and 50.

About Astellas Pharma Inc.

Astellas Pharma Inc., based in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world by providing 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 DM Complications and Kidney diseases. For more information on Astellas Pharma Inc., please visit the company's Website at www.astellas.com/en.

About UCB

UCB, which is based in 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 and the central nervous system. With more than 8,500 people in approximately 40 countries, the company generated revenue of EUR 3.3 billion in 2014. UCB is listed on Euronext Brussels (symbol: UCB).

UCB Japan was established in 1988 and markets a number of products including the allergic disease treatment Zyrtec® Tablets (cetirizine). The anti-epileptic drug E Keppra®, which was launched in September 2010 and Anti-TNF-alpha Antibody Cimzia®, will be a platform for further growth. As a specialty biopharma, UCB Japan is dedicated to making a continuing contribution to the treatment and health of patients with severe diseases such as central nervous system (CNS) disorders and immunology/inflammatory diseases.

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