The results of Japanese Clinical Trials of Anti-TNF-alpha Antibody Certolizumab Pegol including new sub-group Analyses focusing on baseline patient characteristics were Announced at 2014 meeting of leading rheumatology meeting

The additional sub-group analyses of C-OPERA in findings regarding the inhibition of joint structural destruction were reported at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting, November 14 – 19, 2014 in Boston, MA.

The 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 EULAR 2014.

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 co-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) .

As a result of the sub-group analysis of joint destruction after one year focusing on baseline patient characteristics, higher progression of joint destruction was shown in sub-groups with high-positive anti-CCP*[2], positive rheumatoid factor*[3], high disease activity (DAS28(ESR)*[4]), high physical functioning impairment (HAQ-DI*[5]), high CRP level*[6], high MMP-3 level*[7], or joint destruction (mTSS*[8]) at baseline compared to patients without these characteristics in MTX monotherapy. In contrast, CZP + MTX co-therapy inhibited joint destruction even in patients with these characteristics compared to MTX monotherapy.

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*[9], 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: anti-CCP – a kind of autoantibody, used for diagnosis of RA
*3: rheumatoid factor – a kind of autoantibody, used for diagnosis of RA
*4: DAS28(ESR) – Score indicating disease activity of rheumatoid arthritis.
*5: HAQ-DI – Score indicating functional disability
*6: CRP – Acute phase protein indicating intensity of inflammation.
*7: MMP-3 – Proteinase produced by synovial cells, involved in destruction of cartilage.
*8: mTSS – Score indicating joint destruction
*9: 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 40-50 years of age.

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 18,000 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 about 8,500 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2013. 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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