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Astellas Pharma Inc.
UCB Japan Co., Ltd.

Results of Additional Analysis of Data from Japanese Clinical Trial of Anti-TNF-alpha Antibody Certolizumab Pegol Announced at 2015 EULAR Annual European Congress of Rheumatology

Tokyo,Japan,15th June, 2015– Astellas Pharma Inc. ("Astellas"; Tokyo: 4503, headquarters: Chuo-ku, Tokyo; President and CEO: Yoshihiko Hatanaka) and UCB Japan Co., Ltd. ("UCB Japan"; headquarters: Shinjuku-ku, Tokyo; President and Representative Director: Masanobu Kambara; "UCB" when referring to the whole UCB group), which jointly develop and commercialize the pegylated[*1] anti-TNF-α (tumor necrosis factor) antibody certolizumab pegol (CZP) (generic name; brand name in Japan, the US and the EU: Cimzia®) in Japan, are pleased to announce today that the results of additional analyses of data from a study in Japan (C-OPERA) were reported at the European League Against Rheumatism Annual European Congress of Rheumatology (EULAR 2015) held on June 10-13, 2015 in Rome, Italy.

The aim of this analysis was to identify factors associated with better outcomes with CZP (certolizumab pegol) + MTX (methotrexate) compared to placebo + MTX at 1 year in MTX-naïve patients with early-stage rheumatoid arthritis (RA). In the placebo + MTX group, more joint destruction was noted at week 52 in patients with higher baseline DAS28, CRP, mTSS, HAQ-DI and serum MMP-3. Lower clinical remission rates at week 52 were associated with higher baseline DAS28 and CRP. The CZP + MTX group showed better clinical outcomes (higher clinical remission rates and more effective inhibition of joint destruction) compared to the placebo + MTX group, particularly in patients with higher risk of disease progression.

Therefore, the combination of CZP and MTX is expected to be more effective than placebo + MTX at inhibiting disease progression particularly in patients with higher risk of disease progression.

[*1]: PEGylated – PEGylation refers to the modification of an antibody with polyethylene glycol.
[*2]: DAS28(ESR); score indicating disease activity of rheumatoid arthritis, CRP;score indicating level of inflammation, HAQ-DI; score indicating functional disability, mTSS; score indicating joint bone destruction, Serum MPP-3; score indicating bone destruction in relation to synovial proliferation
[*3]: Disease-Modifying Antirheumatic Drugs

About Cimzia

Cimzia is the world's first PEGylated anti-TNF-α (tumor necrosis factor alpha) antibody for the treatment of RA. It has a high affinity for TNF-α, which is involved in the onset and exacerbation of inflammatory diseases such as RA, and selectively inhibits the effects of TNF-α. In global clinical trials, co-therapy with Cimzia and methotrexate (MTX) rapidly improved signs and symptoms of RA and continued to be effective during induction and maintenance therapy. Furthermore, Cimzia prevented progression of structural joint destruction. In clinical trials conducted in Japan, Cimzia reduced signs and symptoms in a rapid and sustained manner and prevented progression of joint destruction irrespective of MTX co-administration. In January 2012, Astellas and UCB signed an agreement to jointly develop and commercialize Cimzia in Japan. It was granted marketing approval in December, 2012 for the treatment of RA with inadequate response to conventional drugs and was launched in March, 2013. In May 2015, Cimzia was indicated for DMARDs*[3] naïve patients with high risk factors of radiographic progression.

In January 2012, Astellas and UCB signed an agreement to jointly develop and commercialize Cimzia in Japan. It was granted marketing approval in December, 2012 for the treatment of RA with inadequate response to conventional drugs and was launched in March, 2013. In May 2015, an additional indication was obtained for the treatment of patients suspected of having higher risk of structural joint injury.

About RA

RA is a progressive autoimmune disease associated with 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. An estimated 650,000 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 at 40-50 years of age.

C-OPERA study

Phase 3 study to evaluate efficacy and safety of CZP + MTX compared to Placebo + MTX in MTX-naïve early RA patients (within one year from RA onset) with poor prognostic factors

References

*Ref: Atsumi T, Yamamoto K, Takeuchi T, et al. The first early rheumatoid arthritis, certolizumab pegol, multicenter, double-blind, randomized, parallel-group study: C-OPERA, in patients fulfilling the 2010 ACR/EULAR classification criteria, demonstrates inhibition of joint damage progression. Presented at the European League Against Rheumatism Meeting 2014, Ann Rheum Dis 73 (Suppl. 2) p484 (Abstract #FRI0278).

About Astellas Pharma Inc.

Astellas Pharma Inc. (http://www.astellas.com/en/corporate/), 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.

About UCB

Based in Brussels, Belgium (www.ucb.com), UCB is a global biopharmaceutical company focused on the discovery, development and marketing of innovative medicines and biotechnology products for severe diseases such as immunology/inflammatory diseases and central nervous system (CNS) disorders. With about 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).

Established in 1988, UCB Japan markets a number of products including the allergic disease treatment Zyrtec® Tablets (cetirizine). The anti-epileptic drug E Keppra®(levetiracetam), which was launched in September 2010 and the TNF-α inhibitor 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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