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Astellas Pharma Inc.
UCB Japan Co., Ltd.

The 2nd Year Results of C-OPERA, a Study of Anti-TNF-alpha Antibody Certolizumab Pegol, Announced at 2015 ACR/ARHP Annual Meeting

– The Clinical benefit of initial 1-year CZP treatment was maintained after discontinuation up to another 1-year –

Tokyo,Japan,10 November, 2015– Astellas Pharma Inc. (Tokyo: 4503, headquarters: Chuo-ku, Tokyo; President and CEO: Yoshihiko Hatanaka; "Astellas") and UCB Japan Co., Ltd. (headquarters: Shinjuku-ku, Tokyo; President and Representative Director: Masanobu Kambara: "UCB Japan"; when referring to the whole UCB group: "UCB"), 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 newly obtained data of a study in Japan (C-OPERA) were reported at the 2015 ACR/ARHP Annual Meeting held on November 6-11, 2015 in San Francisco, the United States of America.

C-OPERA is the 1-year double-blind, placebo-controlled, randomized study evaluating the efficacy and safety of CZP in combination with maximally tolerable dose of methotrexate (MTX) by comparison with MTX monotherapy in Japanese MTX naïve early rheumatoid arthritis (RA) patients with poor prognostic factors, with a subsequent 1-year open label follow up period. In the previous report, CZP + MTX showed significantly higher prevention of radiographic joint damage and significantly higher induction of clinical remission after one year compared to MTX monotherapy[*2].

The companies newly reported the 2nd year results of the study. In this period, CZP was discontinued at the end of the first year, and then all patients had been followed for another year with MTX monotherapy. As a result, patients who were previously treated with CZP for the first year had less joint damage progression and higher clinical remission rate compared to those who were treated with MTX monotherapy throughout two years at the end of the second year. These results suggested that the impact of initial 1-year CZP treatment was maintained after discontinuation up to two years.

Based on the results, indicating usefulness of CZP+MTX to early RA patients with high risk of joint damage progression throughout 1 year even after CZP discontinuation, the companies expect that CZP+MTX will further contribute to inhibition of disease progression in such RA patients.

[*1]: PEGylated – PEGylation refers to the modification of an antibody with polyethylene glycol.
[*2]: Atsumi T. Ann Rheum Dis 2014;73(S2):484

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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.

*[3]: Disease-Modifying Antirheumatic Drugs

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

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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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