Announcement of Approval of Additional Indication for the TNF-α inhibitor Certolizumab Pegol (Generic Name) in Japan

Tokyo, Japan, May 26, 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 Kanbara; "UCB" when referring to the whole UCB group), which jointly develop and commercialize the pegylated[*1] TNF-α inhibitor (tumor necrosis factor) certolizumab pegol (generic name; brand name in Japan, the US and the EU: Cimzia®) in Japan, are pleased to announce today that an additional indication (partial modification of approval) has been approved.

In association with the approval of the additional indication, the package insert was revised as shown below:

(The strike-through statements shown below are to be deleted, and the underlined statements are to be added.)

[Indications]
Treatment of Rheumatoid arthritis~~ not responding to conventional therapy~~ (including inhibition of progression of bone structural damage)
[Indications related to Precautions]

~~Use Cimzia only when apparent clinical symptoms due to the disease remain even after appropriate treatments with at least one anti-rheumatoid agent. (except biological drug)~~ In principle, the use of Cimzia® is limited to RA patients who have had an inadequate response to conventional therapy. However, although Cimzia® can be given to patients with high risk of progression of structural damage even they have not received prior treatment with anti-rheumatic drugs, evaluate patient's conditions and judge the necessity for use of this agent carefully, after referring to recent guidelines and so on.

As a rule, the use of Cimzia® is restricted to rheumatoid arthritis (RA) patients with inadequate response to existing therapies. However, this new approval makes it possible to administer Cimzia® to RA patients without previous treatment with anti-RA drugs when they present a high risk for progression of structural joint destruction.

The additional indication was approved based on the results of a new clinical trial conducted in Japan in early-stage RA patients without a history of previous therapy with methotrexate (MTX) in which Cimzia® inhibited progression of structural joint destruction and improved signs and symptoms in RA[*Ref].

Astellas and UCB believe that the additional indication for certolizumab pegol will contribute to further improvement in the treatment of RA.

Astellas will make a milestone payment to UCB following this approval for the additional indication. The impact of this payment which was reflected in Astellas' current fiscal year (from April 1, 2015 to March 31, 2016) financial forecast.

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. It has an extended blood half-life due to PEG moiety attached to its Fc-free Fab region*2 of the humanized antibody and is effective in the treatment of RA when injected subcutaneously every two weeks or once a month. 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 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.

Cimzia® is supplied in the form of a prefilled syringe to facilitate self-administration by RA patients at the discretion of healthcare professionals.

Astellas and UCB jointly develop and commercialize Cimzia® in Japan. Cimzia® was granted marketing authorization in Japan in December 2012 and was launched in March 2013.

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.

*1: PEGylated – PEGylation refers to the modification of an antibody with polyethylene glycol.

*2: 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

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. It is committed to becoming a global category leader in 5 core research fields: Urology, Immunology (including Transplantation) and Infectious diseases, Oncology, Neuroscience and DM Complications and Kidney diseases.

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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