

## Announcement of an Application for the Additional Indication for the Anti-TNF- $\alpha$ Antibody Certolizumab Pegol (Generic Name)

**Tokyo, Japan, 25 June, 2014** – Astellas Pharma Inc. (“Astellas”; TSE: 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: Joel Peterson; “UCB” for the whole UCB group), which jointly develop and commercialize the pegylated<sup>\*1</sup> anti-TNF- $\alpha$  (tumor necrosis factor) antibody certolizumab pegol (generic name; brand name in Japan, the US and the EU: Cimzia<sup>®</sup>) in Japan, are pleased to announce today that they have filed an application for the additional indication.

At present, the use of Cimzia<sup>®</sup> is restricted to patients of rheumatoid arthritis (RA) with inadequate response to existing therapies. The new application will make it possible to administer Cimzia<sup>®</sup> to RA patients without previous treatment with anti-RA drugs when rapid progression of structural joint destruction is expected.

The application is based on the findings obtained regarding the inhibition of progression of structural joint destruction, clinical efficacy and safety in the PIII C-OPERA clinical trial in which RA patients without previous treatment with methotrexate (MTX) received certolizumab pegol (CZP) and MTX or MTX alone within one year after onset of RA.

Cimzia<sup>®</sup> 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<sup>\*2</sup>, and is effective in the treatment of RA as a subcutaneous injection either every two weeks or once a month. In global clinical trials, co-therapy with Cimzia<sup>®</sup> and MTX rapidly improved signs and symptoms of RA and continued to be effective during induction and maintenance therapy. Furthermore, Cimzia<sup>®</sup> prevented progression of joint bone destruction. In clinical trials conducted in Japan, Cimzia<sup>®</sup> showed rapid and sustained reduction in signs and symptoms and prevented progression of joint destruction when administered with or without MTX. Cimzia<sup>®</sup> 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<sup>®</sup> in Japan. Cimzia<sup>®</sup> was granted Japanese marketing approval in December, 2012 and was launched in March, 2013. Astellas will make a milestone payment to UCB upon additional indication submission. Impact of this payment on Astellas’ financial results of the current fiscal year ending March 31, 2015 will be immaterial.

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

- \*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.



### **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 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](http://www.astellas.com/en).

### **About UCB**

UCB, which is based in Brussels, Belgium ([www.ucb.com](http://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<sup>®</sup> Tablets (cetirizine). The anti-epileptic drug E Kepra<sup>®</sup>, which was launched in September 2010 and Anti-TNF-alpha Antibody Cimzia<sup>®</sup>, 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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