



## UCB and Astellas announce agreement to jointly develop and commercialize Cimzia<sup>®</sup> (certolizumab pegol) in Japan

- *Astellas and UCB partner to bring certolizumab pegol to rheumatoid arthritis patients in Japan*
- *UCB files certolizumab pegol for marketing authorisation with the Japanese Ministry of Health, Labour and Welfare*

**Tokyo, Japan and Brussels, Belgium, 1<sup>st</sup> February 2012, 0600 CET – regulated information** - Astellas Pharma Inc. (“Astellas”) and UCB announced today that the companies entered into an agreement on 31<sup>st</sup> January 2012 to jointly develop and commercialize certolizumab pegol (Cimzia<sup>®</sup>) for rheumatoid arthritis (RA) in Japan. Under this agreement, UCB will manufacture and supply the product for commercialization. Astellas will manage the distribution exclusively (Astellas books the sales), and both Astellas and UCB will co-develop and co-commercialise certolizumab pegol in Japan.

Certolizumab pegol is the only PEGylated anti-Tumor Necrosis Factor (TNF)-alpha. It has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha. Positive Japanese study results showing that certolizumab pegol, with or without methotrexate (MTX), was associated with significant inhibition of structural joint damage progression and significant improvements in physical function compared to placebo, were published at the American College of Rheumatology's (ACR) 2011 Annual Scientific Meeting.\* In January 2012 and based on these data, UCB filed certolizumab pegol for marketing authorisation with the Japanese Ministry of Health, Labour and Welfare for the indication of rheumatoid arthritis in patients who respond insufficiently to current therapies.

Under the terms of the agreement, UCB will receive an initial cash payment and UCB is also eligible to receive clinical and regulatory milestones as well as commercial milestones. The impact from this agreement on Astellas' current fiscal year, ending March, 2012 will not be material.

“UCB is pleased to announce this partnership with Astellas and believes that Astellas' excellence in research and development as well as its strong rheumatology sales and marketing infrastructure in Japan should ensure that the value of certolizumab pegol is optimised for patients and healthcare professionals.” said Mark McDade, Executive VP, Chief Operating Officer, UCB.

“This partnership re-enforces both companies' joint commitment to improving and benefiting the lives of people in Japan living with serious immunological diseases.”

“Astellas expects to contribute to the management of the treatment of rheumatoid arthritis and provide a new therapeutic option by adding certolizumab pegol to our products in the field of immunology and inflammation which are available in Japan.” said Mr. Yoshihiko Hatanaka, President and CEO of Astellas Pharma Inc.

\*For more information about the certolizumab pegol data, please read the [press release](#) distributed at the ACR 2011 in Chicago.



### **About CIMZIA®**

The U.S. Food and Drug Administration (FDA) has approved Cimzia® for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderately to severely active rheumatoid arthritis. Cimzia® in combination with MTX, is approved in the EU for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.

### **Cimzia® (certolizumab pegol) in European Union/ EEA important safety information**

Cimzia® was studied in 2367 patients with RA in controlled and open label trials for up to 57 months. The commonly reported adverse reactions (1-10%) in clinical trials with Cimzia® and post-marketing were viral infections (includes herpes, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopaenia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritis (any sites), hepatitis (including hepatic enzyme increase) and injection site reactions. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic edema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 5% of patients discontinued taking Cimzia® due to adverse events vs. 2.5% for placebo.

Cimzia® is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections or moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving Cimzia®. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with Cimzia®. Treatment with Cimzia must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop Cimzia® if infection becomes serious. Before initiation of therapy with Cimzia®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, Cimzia® therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with Cimzia®. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with Cimzia®.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including Cimzia® who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Cimzia®. Carriers of HBV who require treatment with Cimzia® should be



*closely monitored and in the case of HBV reactivation Cimzia® should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.*

*TNF antagonists including Cimzia® may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a patient develops any of these adverse reactions, Cimzia® should be discontinued and appropriate therapy instituted.*

*With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with Cimzia®.*

*Adverse reactions of the hematologic system, including medically significant cytopenia, have been infrequently reported with Cimzia®. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia®. Consider discontinuation of Cimzia® therapy in patients with confirmed significant haematological abnormalities.*

*The use of Cimzia® in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, Cimzia® should not be administered concurrently with live vaccines or attenuated vaccines. The 14-day half-life of Cimzia® should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on Cimzia® should be closely monitored for infections.*

*Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision November 2011.*

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/001037/WC500069763.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf)

### **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 vascular system. It is estimated that 0.65 million people live with RA in Japan and 5 million people globally. Prevalence is not split evenly between genders, since 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.

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***About Astellas Pharma Inc.***

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of 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 Diabetes Mellitus (DM) Complications and Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company Website at [www.astellas.com/en](http://www.astellas.com/en).

***About UCB***

UCB, 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 or of the central nervous system. With more than 8 500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2010. UCB is listed on Euronext Brussels (symbol: UCB).

***Forward looking statements***

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.