UBC announces data on certolizumab pegol for patients with moderate to severe rheumatoid arthritis at American College of Rheumatology 2012 Congress

- Efficacy in maintenance of clinical response versus placebo was demonstrated in patients with and without prior anti-TNF therapy in a post hoc analysis of the DOSEFLEX study
- No new safety signals in long-term safety update of certolizumab pegol in studies of patients with moderate to severe rheumatoid arthritis

Slough, UK – November 13th, 2012 – UCB today announced findings from studies that evaluated the long-term outcomes, dosing and safety of Cimzia® (certolizumab pegol) for adults with moderate to severe rheumatoid arthritis (RA). The data were presented at the American College of Rheumatology’s (ACR) 2012 Annual Scientific Meeting in Washington, D.C., November 10-14, 2012.

"Because rheumatoid arthritis is a chronic disease that requires ongoing management, it is important to evaluate anti-TNF therapy in the long-term clinical setting. Studying this can help us to better understand long-term outcomes for patients who wish to maintain their health-related quality of life and ability to participate in daily activities,” said Dr. Roy Fleischmann, Clinical Professor, Department of Internal Medicine, University of Texas Southwestern Medical Center.

DOSEFLEX was a 34 week, phase 3b study, with a 16 week open label run-in phase, followed by randomization into a double-blind, placebo controlled phase that was designed to compare the clinical efficacy of two maintenance dosing regimens of certolizumab pegol (200 mg every two weeks versus placebo and 400 mg every four weeks versus placebo*) in combination with weekly MTX.

At week 34, the post-hoc analysis showed that ACR20 scores in patients with and without prior anti-TNF exposure were 74.4% compared with 55.6% in the 200 mg every two weeks group, and 61.5% compared with 70.0% in the 400 mg every four weeks group.

The study enrolled 333 patients with active RA who had experienced an incomplete response to MTX. The primary efficacy endpoint was ACR20 response at week 34. ACR20 indicates a 20 percent improvement in tender joint count or swollen joint count, as well as a 20 percent improvement in three of five other criteria, including patient and physician assessment of disease activity, patient assessment of pain and physical function, and levels of acute phase reactant (either the C-reactive protein level or the erythrocyte sedimentation rate).

In the DOSEFLEX study adverse events (AE) were comparable amongst the certolizumab pegol and placebo groups. AEs belonged to the system organ class infections and infestations (4.3% in 200 mg every two week group and 0% in 400 mg every four week or placebo groups).
A long-term safety update of certolizumab pegol in patients with active moderate to severe RA showed that no new safety signals were associated with treatment during the duration of the analysis. The update included 4,049 patients who received certolizumab pegol with a mean exposure of 2.1 years. The pooled analysis included 10 completed randomized controlled trials (RCTs) and their open-label extensions of certolizumab pegol in patients with RA. The cutoff date was November 30, 2011. Serious infectious events were the most common serious adverse events. In total, 43 tuberculosis infections occurred in 43 patients, 58 deaths occurred in certolizumab pegol patients (incidence rate [IR]: 0.63/100 PY) as a result of 19 cardiovascular events, 13 infections, 13 malignancies, and 18 other causes. Sixty-five certolizumab pegol patients in all studies developed malignancies (event rate: 0.72/100 PY), with 60 patients developing solid tumors (event rate: 0.67/100 PY) and five patients developing lymphoma (event rate: 0.05/100 PY). The safety profile of certolizumab pegol in this long-term safety analysis was consistent with previous experience, with no new safety signals identified.

* Certolizumab pegol in combination with methotrexate is approved in the European Union as a maintenance regimen of 200 mg every two weeks. The certolizumab pegol dosing regimen of 400 mg every four weeks is not approved in the European Union.

For further information
Scott Fleming, Head of UK Communications
T +447702777378, scott.fleming@ucb.com

Funmi Ahmed-Onibudo, Brand Communications Manager
T +441753 67 7296, funmi.ahmed-onibudo@ucb.com

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) is an autoimmune disease where the body’s immune system, which usually fights infection, attacks itself. This causes inflammation of the joints and normally affects the wrists, fingers, thumbs, feet and ankles causing pain and swelling but can also affect the entire body. RA affects 580,000 people in England, which suggests that over 690,000 adults in the UK live with the condition.

About Cimzia®
Certolizumab pegol is the first PEGylated anti-TNF (Tumour Necrosis Factor alpha) to be launched for the treatment of moderate to severe active RA, in combination with methotrexate (MTX), in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate. Certolizumab pegol has also been approved for use alone as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate, in the same patient population.

Certolizumab pegol is a monoclonal antibody with high specificity for human TNF-alpha, selectively neutralising the pathophysiological effects of TNF-alpha. Over the past decade, TNF-alpha has emerged as a major target of basic research and clinical investigation. This cytokine plays a key role in mediating inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. 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 July 2012.


About UCB
UCB, Brussels, Belgium (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 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. 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.

References


