New Cimzia® (certolizumab pegol) Data Show a Significant, Rapid Clinical Response and Reduced Disease Activity Among Diverse Patient Populations with Active Rheumatoid Arthritis (RA)

- **The REALISTIC phase IIIb clinical trial demonstrated statistically significant improvements among a broad active RA patient population representing routine clinical practice meeting its primary endpoint at week 12**
- **Trial results showed Cimzia® provided rapid improvements in disease activity and physical function as early as week 2 of treatment and through week 12**

ATLANTA – November 9, 2010, 08:00 (EST) – The addition of Cimzia® (certolizumab pegol; CZP) to current therapy was associated with a rapid clinical response, improved function and reduced disease activity in a diverse group of adult rheumatoid arthritis (RA) patients reflecting those seen in daily clinical practice (including those with prior TNF-inhibitor use). These positive clinical trial data were presented during the American College of Rheumatology's (ACR) 2010 Annual Scientific Meeting in Atlanta, November 7-11. Cimzia® is approved for the treatment of adults with moderately to severely active rheumatoid arthritis.

"Many patients live with little relief from the painful symptoms of rheumatoid arthritis due to failed therapies or the severity of the condition," said Roy Fleischmann, MD, clinical professor in the Department of Internal Medicine at the University of Texas Southwestern Medical School. "These data emphasize that treatment with Cimzia® can substantially provide rapid improvements and help reduce disease activity regardless of the patient's disease history."

The data presented were from the REALISTIC (RA Evaluation in Subjects Receiving TNF Inhibitor Certolizumab Pegol) multicenter phase IIIb study, which included a 12-week, randomized, double-blind (DB), placebo-controlled phase followed by an open-label extension (OLE) (≥16 weeks). REALISTIC was designed to investigate the safety and efficacy of CZP in a broad patient population with active RA more closely resembling routine clinical practice, versus the pivotal trials, including patients with/without prior TNF-inhibitor exposure, with/without concomitant methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs); and varying lengths of disease duration.*

The primary endpoint of an ACR20 score at week 12 was met. At Week 12, more than half (51.1%) of patients in the CZP treatment group achieved ACR20 response versus the control group (25.9%). Additional efficacy evaluated in the trial included ACR50/70 response rates, as well as the DAS28[CRP] disease activity score and the Health Assessment Questionnaire-Disability Index (HAQ-DI) measuring physical function.

Clinical responses among patients in the CZP treatment group were rapid. ACR 20/50 responses were significantly superior to control (31.8% vs 8.5% and 9.6% vs 1.4%,

p<0.001 for both) from the first time point (week 2) onwards. Significant improvements in DAS28[CRP] were reported among patients treated with CZP vs. the placebo group. In addition, CZP patients reported rapid and significant improvements in HAQ-DI vs. placebo at the first time point measured (week 2).

Similar ACR20 responses were seen across the various patient populations regardless of baseline disease duration or activity; baseline use of methotrexate; or prior use of TNF-inhibitors. ACR50 and ACR70 responses at week 12 were 26.6% and 13% for patients treated with CZP compared to the placebo group (9.9% and 2.8% respectively).

Treatment with CZP was generally well tolerated. Adverse and serious adverse event rates were comparable between CZP and placebo treatment groups with no new safety signals observed through week 12. The most common serious infections were lower respiratory tract and lung infections. The most common adverse events were infections and infestations, musculoskeletal and connective tissue disorders, and nervous system disorders.

** 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*

For full study information, please see:
http://www.abstracts2view.com/acr/titleindex.php?num=E&page=2

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About REALISTIC*
REALISTIC (RA Evaluation in Subjects Receiving TNF Inhibitor Certolizumab Pegol) is a multicenter phase IIIb trial in patients with active rheumatoid arthritis who have shown inadequate response to disease-modifying antirheumatic drugs, including patients with/without prior TNF-inhibitor exposure, with/without concomitant methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs); and varying lengths of disease duration. The study demonstrated that – in a diverse group of RA patients reflecting those seen in daily clinical practice (including those with prior TNF-inhibitor use) – addition of CZP to current therapy was associated with a rapid clinical response consistent in all strata, improved function and reduced disease activity.

About CIMZIA®
Cimzia® is the only PEGylated anti-TNF (Tumor Necrosis Factor). Cimzia® has a high affinity for human TNF-alpha, selectively neutralizing 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 pathological inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. 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.

Global abbreviated prescribing information
Name of the medicinal product: *Cimzia® (Certolizumab pegol)* ***Pharmaceutical form:*** *Solution for injection. Each pre-filled syringe contains 200 mg certolizumab pegol in one ml.* ***Therapeutic indications:*** *Cimzia®, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARD) including methotrexate, has been inadequate. Cimzia® can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Cimzia® has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.* ***Posology and method of administration:*** *Cimzia® treatment should be initiated and supervised by a specialist physician. After proper training in injection technique, patients may self-inject with Cimzia® if considered appropriate by the physician and with medical follow-up as necessary. The recommended starting dose of Cimzia® for adult patients with RA is 400 mg (as 2 injections of 200 mg each on one day) at weeks 0, 2 and 4, followed by a maintenance dose of 200 mg every 2 weeks. MTX should be continued during treatment with Cimzia® where appropriate. The total content (1 ml) of the pre-filled syringe should be administered as subcutaneous injection only. Suitable sites for injection would include the thigh and abdomen.*

The safety and efficacy of Cimzia® in children and adolescents below age 18 years have not yet been established. No data are available. No dose recommendations can be made for patients with renal and hepatic impairment as Cimzia® has not been studied in these patient populations. No dose adjustment is required in the elderly (≥ 65 years old) as population pharmacokinetic analyses showed no effect on age. ***Contraindications:*** *Hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections, moderate to severe heart failure (NHYA classes III/IV).* ***Special warnings and precautions for use:*** *Serious infections, sepsis, tuberculosis (including miliary, disseminated and extrapulmonary disease) and opportunistic infections (e.g. histoplasmosis, nocardia, candidiasis) have been reported in patients receiving Cimzia®. Some of these events have been fatal. Patients must be monitored closely for signs and symptoms of infections including tuberculosis before, during and up to 5 months after treatment with Cimzia®. Patients who develop a new infection should be monitored closely. Administration of Cimzia® should be discontinued if a patient develops a new serious infection until the infection is controlled. Physicians should exercise caution when considering the use of Cimzia® in patients with a history of recurring infection, or with underlying conditions which may predispose patients to infections including the use of concomitant immunosuppressive medications. Before initiation of therapy with Cimzia®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection including a detailed medical history for patients with a personal history of tuberculosis, with possible previous exposure to others with active tuberculosis, and with previous and/or current use of immunosuppressive therapy. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with Cimzia® and the benefit/risk balance of therapy with Cimzia® should be very carefully considered. 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®. TNF blockers including Cimzia® may increase the risk of reactivation of Hepatitis B Virus (HBV) in patients who are chronic carriers of the virus. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating Cimzia® therapy. Carriers of HBV who require treatment with TNF antagonists should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for up to 5 months after therapy, especially if the patient is on concomitant corticosteroid therapy. In patients who develop HBV reactivation, Cimzia® should be discontinued and effective antiviral therapy with appropriate supportive treatment should be initiated. As the potential role of TNF antagonist therapy in the development of malignancies is not known, caution should be exercised when considering TNF antagonist therapy for patients with a history of malignancy or when considering continuing treatment in patients who develop malignancy. 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.*

In clinical studies with Cimzia® and other TNF antagonists, more cases of lymphomas and other malignancies have been reported among patients receiving TNF antagonists than in control patients receiving placebo. In the post marketing setting, cases of leukaemia have been reported in patients treated with a TNF antagonist. There is an increased background risk for lymphoma and leukaemia in RA patients with long-standing, highly active, inflammatory disease, which complicates the risk estimation. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF antagonists (initiation of therapy ≤ 18 years of age) in the post marketing setting. Approximately half the cases were lymphomas. The other cases represented a variety of different malignancies and included rare malignancies usually associated with immunosuppression. A risk for the development of malignancies in children and adolescents treated with TNF antagonists cannot be excluded.

Caution should be exercised when using any TNF antagonist in chronic obstructive pulmonary disease patients, as well as in patients with increased risk for malignancy due to heavy smoking. Cases of congestive heart failure have been reported in RA patients receiving Cimzia® and hence it should be used with caution in patients with mild heart failure (NYHA class I/II). Treatment with Cimzia® must be discontinued in patients who develop new or worsening symptoms of congestive heart failure. Adverse reactions of the hematologic system, including medically significant cytopaenia (e.g. leukopaenia, pancytopaenia, thrombocytopaenia) have been reported with Cimzia®. All patients should be advised 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®. Discontinuation of Cimzia® therapy should be considered in patients with confirmed significant haematological abnormalities. Use of TNF antagonists has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease, including multiple sclerosis. In patients with pre-existing or recent onset of demyelinating disorders, the benefits and risks of TNF antagonist treatment should be carefully considered before initiation of Cimzia® therapy. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with Cimzia®. Severe hypersensitivity reactions have been reported rarely following Cimzia® administration in trials. If severe reactions occur, administration of Cimzia® should be discontinued immediately and appropriate therapy instituted. Since TNF mediates inflammation and modulates cellular immune responses, the possibility exists for TNF antagonists, including Cimzia®, to cause immunosupression, affecting host defences against infections and malignancies. Treatment with Cimzia® may result in the formation of antinuclear antibodies (ANA) and, uncommonly, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Cimzia®, treatment must be discontinued. As no data are available, live vaccines or attenuated vaccines should not be administered concurrently with Cimzia®.

The use of Cimzia® in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections and neutropenia. 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. Interference with certain coagulation assays has been detected in patients treated with Cimzia®. Cimzia® may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities. This effect has been observed with the PTT-Lupus Anticoagulant (LA) test and Standard Target Activated Partial Thromboplastin time (STA-PTT) Automate tests from Diagnostica Stago, and the HemosIL APTT-SP liquid and HemosIL lyophilized silica tests from Instrumentation Laboratories. Other aPTT assays may be affected as well. There is no evidence that Cimzia® therapy has an effect on coagulation in vivo. After patients receive Cimzia®, careful attention should be given to interpretation of abnormal coagulation results. Interference with thrombin time (TT) and prothrombin time (PT) assays have not been observed. Caution should be exercised when treating the elderly and particular attention paid with respect to occurrence of infections. ***Fertility, pregnancy and lactation:*** *Cimzia® should not be used in pregnancy due to lack of adequate data. Women of childbearing potential should use adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Cimzia® administration. There is insufficient information on the excretion of certolizumab pegol in human or animal breast milk. Since immunoglobulins are excreted into human breast milk, a risk to the breast-feeding child cannot be excluded. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Cimzia® should be made taking into account the benefit of breast-feeding to the child and the benefit of Cimzia® therapy to the woman.* ***Undesirable effects:*** *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® 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), 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, pancytopaenia, 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. Please refer to the full Prescribing Information in your country before prescribing. ***Legal Classification:*** *Medical product subject to medical prescription.* ***Date of revision:*** *26th August 2010.* ***Marketing authorisation holder:*** *UCB Pharma, S.A. Allée de la Recherche 60 B-1070 Bruxelles Belgium.* ***Marketing authorisation number(s):*** *EU/1/09/544/001-002.* ***Date of authorisation:*** *October 2009.*

Please see full prescribing information before prescribing. This can be accessed at:
www.ema.europa.eu/humandocs/PDFs/EPAR/cimzia/emea-combined-h1037en.pdf

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 3.1 billion in 2009. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statement
This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.