Cimzia®, the only PEGylated anti-TNF, approved in Europe and available in a syringe designed in partnership with OXO Good Grips®

- **Cimzia® (*certolizumab pegol*), in combination with *methotrexate* (MTX), approved by the European Commission for the treatment of moderate to severe active rheumatoid arthritis (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**
- **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 MTX.**

Brussels, BELGIUM, 5 October, 2009 – 15:30 (CEST) – regulated information – UCB announced today that the European Commission (EC) approved Cimzia®, in combination with MTX, 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.

Cimzia® has been approved to be administered as a subcutaneous injection using the new prefilled syringe designed in partnership with OXO Good Grips®, a brand dedicated to providing innovative consumer products that make everyday living easier. The UCB and OXO Good Grips® partnership resulted in a redesign of the traditional syringe with the aim of making self-administration easy for people living with RA. The syringe is designed for use by patients with different grip styles and strengths and it provides measurable improvements in the patient experience.

"Cimzia® has been shown to rapidly reduce the rate of progression of joint damage and to improve measurements of patients' physical function," said Dr Prof. Dr. Iris Loew-Friedrich, Chief Medical Officer of UCB. "These are areas of a key concern for rheumatologists when treating patients with active RA, and we therefore believe Cimzia® provides an important new treatment option."

In the RAPID 1 and RAPID 2 clinical trials statistically significantly greater ACR20 and ACR50 responses were achieved from Week 1 and Week 2, respectively, in both clinical trials compared to placebo. Responses were maintained through Weeks 52 (RAPID 1) and 24 (RAPID 2). Additionally, the RAPID 1 open label extension study, in patients who responded to treatment with Cimzia®, showed that the improvements gained in ACR20/50/70 scores were sustained for two years in patients receiving Cimzia®, in combination with MTX.

Radiographic data showed inhibition of the progression of structural joint damage, was observed at 24 weeks of treatment, in RA patients treated with Cimzia® in combination

with MTX and sustained for 100 weeks (100 week data are results from the open-label extension study of RAPID 1).

The recommended starting dose of Cimzia® for adult patients with RA is 400mg (as 2 injections of 200mg each on one day) at weeks 0, 2 and 4, followed by a maintenance dose of 200mg every 2 weeks. MTX should be continued during treatment with Cimzia where appropriate.

The European approval is supported by data from a comprehensive clinical development programme, involving more than 2,300 patients with RA and over 4,000 patient-years experience.

As observed with other anti-TNF's in the pivotal clinical trials reported serious adverse reactions included infections (including tuberculosis) and malignancies (including lymphoma). The most common adverse reactions belonged to the system organ classes Infections and Infestations, reported in 15.5% of patients on Cimzia® and 7.6% of patients on placebo, and General disorders and administration site conditions, reported in 10.0% of patients on Cimzia® and 9.7% of patients on placebo. A pooled analysis of the safety data showed there was a low incidence of injection site pain (1.5%) and a low level of discontinuations due to adverse events (5%). Cimzia® demonstrated a favorable risk-benefit profile in patients with at least up to two years of drug exposure.

The U.S. Food and Drug Administration (FDA) recently approved Cimzia®, together with MTX, for the treatment of adult patients with moderately to severely active RA.

For further information
Scott Fleming, Global Communications Manager – Immunology
T +44.770.277.7378, scott.fleming@ucb.com

Richard Simpson, Investor Relations, UCB
T +32.2.559.9494, richard.simpson@ucb.com

Michael Tuck-Sherman, Investor Relations, UCB
T +32.2.559.9712, michael.tuck-sherman@ucb.com

Nancy Nackaerts, External Communications, UCB
M: +32 473 86 44 14, nancy.nackaerts@ucb.com

Gretchen Holt, Corporate Communications Manager OXO
T +1212 242 3333, gholt@oxo.com

Notes To Editors

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® was approved in Switzerland for induction of a clinical response and for the maintenance of a clinical response and a remission in patients with active Crohn's disease who have not responded adequately to conventional treatment in September 2007. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.

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About RAPID 1
The Phase III double-blind placebo-controlled trial, involving 982 adults, was designed to establish the efficacy and tolerability of certolizumab pegol together with MTX, in the treatment of active RA in patients who did not adequately respond to conventional treatment. Patients were randomly allocated to receive one of three treatment regimens: 393 patients received certolizumab pegol 400 mg and at Weeks 0, 2 and 4, then 200 mg every two weeks; 390 patients received certolizumab pegol 400 mg every 2 weeks; 199 patients received placebo every 2 weeks. RAPID 1 met co-primary endpoints: ACR20 response rate at Week 24 and change from baseline in mTSS at Week 52.

About RAPID 2
This Phase III double-blind placebo-controlled trial, involving 619 patients with active adult-onset RA was designed to evaluate the efficacy and tolerability of subcutaneous (SC) liquid certolizumab pegol (200 and 400 mg) together with MTX every 2 weeks compared to placebo together with MTX in patients with active RA despite ≥ 6 months treatment with MTX. Patients were randomly allocated to receive one of three treatment regimens: 246 patients received certolizumab pegol (liquid formulation) 400 mg and at Weeks 0, 2 and 4, then 200 mg every two weeks; 246 patients received certolizumab pegol (liquid formulation) 400 mg every 2 weeks; 127 patients received placebo every 2 weeks. RAPID 2 met its primary endpoint ACR20 response rate at Week 24, and secondary endpoints: change from baseline in mTSS, ACR 50 and ACR 70 responses at Week 24. Significantly more patients in the certolizumab pegol 200 and 400 mg groups achieved an ACR20 response versus placebo (p≤ 0.001); rates were 57.3%, 57.6%, and 8.7%, respectively. Certolizumab pegol 200 and 400 mg also significantly inhibited radiographic progression; mean changes from baseline in mTSS at Week 24 were 0.2 and –0.4, respectively, versus 1.2 for placebo (rank analysis p≤ 0.01). Certolizumab pegol treated patients reported rapid and significant improvements in physical function versus placebo (p≤ 0.001).

Important safety information
The most common adverse reactions belonged to the system organ classes Infections and infestations, reported in 15.5% of patients on Cimzia and 7.6% of patients on placebo, and General disorders and administration site conditions, reported in 10.0% of patients on Cimzia and 9.7% of patients on placebo.The most serious adverse reactions were serious infections (including tuberculosis and histoplasmosis), malignancies (including lymphoma) and heart failure. A pooled analysis of the safety data show there was a low incidence of injection site pain (1.5 percent) and low level of discontinuations due to adverse events.

Cimzia® is contraindicated in patients with active tuberculosis or other severe infections such as sepsis, abscesses and opportunistic infections and in patients with moderate to severe heart failure. Before initiation of Cimzia®, evaluate patients for both active or inactive (latent) tuberculosis infection. Monitor patients for the development of signs and symptoms of infection during and after treatment with Cimzia®. If an infection develops, monitor carefully, and stop Cimzia® if infection becomes serious.

Use of TNF blockers, including Cimzia®, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus, of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease, in the formation of autoantibodies and uncommonly in the development of a lupus-like syndrome or of severe hypersensitivity reactions following Cimzia administration. If a patient develops any of these adverse reactions, Cimzia® should be discontinued and appropriate therapy instituted.

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 biological DMARDS such as anakinra, abatacept and rituximab 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.

Please see full prescribing information before prescribing.

About UCB
UCB, Brussels, Belgium (www.ucb.com) is a biopharmaceutical company dedicated to the research,

development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing approximately 10,000 people in over 40 countries, UCB generated revenue of EUR 3.6 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

About OXO

Founded in 1990 on the concept of Universal Design, OXO's mission is to create consumer household products that ease the tasks of everyday life for the widest range of users possible. Since the original 15 items were introduced, the OXO collection has grown to more than 800 strong covering areas for cooking, cleaning, gardening, storing, organizing and lighting. Today OXO Good Grips products are sold in 54 countries and are included in the permanent collections of numerous museums. The company has won more than 100 design and business awards worldwide. OXO is very frequently used as a case study on how a well-executed Universal Design philosophy can be a successful business strategy. OXO is owned by Helen of Troy Limited, a leading designer, producer and global marketer of brand-name personal care and household consumer products.

Forward-looking statements

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.