RAPID-PsA study showed that Cimzia® (certolizumab pegol) improved active psoriatic arthritis, in patients both with and without prior TNF exposure

- **ACR20 response rates with certolizumab pegol were higher than placebo at weeks 12 and 24 with response observed as early as week 1 in some patients**

- **At week 24 improvement in signs and symptoms of psoriatic arthritis was observed in patients with and without prior anti-TNF exposure as well as improvement in associated skin and nail psoriasis**

- **Certolizumab pegol is not approved for the treatment of PsA. UCB filed global regulatory submissions for certolizumab pegol in PsA earlier this year**

**Slough, UK, April 25, 2013:** Today at the British Society of Rheumatology annual meeting UCB presented results from the RAPID™-PsA study. Data presented from this phase 3 study showed that compared to placebo, certolizumab pegol provided improvements in the signs and symptoms of psoriatic arthritis (PsA) in adult patients, both with and without prior anti-TNF (tumor necrosis factor) exposure.

The data, taken from RAPID-PsA (a 158-week, Phase III, multicentre study in PsA patients) showed that ACR20 response at Week 12 was significantly higher in the CZP 200 mg Q2W and CZP 400 mg Q4W arms vs PBO. Response rates were observed as early as Week 1 and maintained to Week 24. The majority of the ACR response rate was achieved by Week 12. No new safety signal was observed using CZP in PsA as compared with safety of CZP in RA.

"The study has produced informative clinical data. It has enabled us to observe rapid responses that may be maintained for extended periods and can positively impact on the patient’s quality of life” said Professor Ade Adebajo, Consultant Rheumatologist at Barnsley Hospital NHS Foundation Trust. "To have an additional effective therapy option for patients suffering with psoriatic arthritis would be welcomed by those of us treating patients with this chronic disease”.

At Week 24, ACR response rates were similar between CZP arms and greater vs PBO irrespective of prior anti-TNF exposure. Treatment with CZP resulted in statistically significant improvements in physical function compared to placebo, measured by mean change in HAQ-DI at week 24 (combined CZP groups: -0.50 vs. placebo: -0.19, p<0.001); the difference between CZP and placebo treated patients was seen by week 2 (-0.23 vs. -0.13, p=0.005).

Additionally, for patients with baseline nail disease, the mNAPSI change from baseline at week 24 was 1.6 with CZP 200 mg Q2W and -2.0 with CZP 400 mg Q4W vs. -1.1 with placebo (p=0.003 and p<0.001, respectively). Lastly, in patients with ≥3% BSA psoriasis
involvement at baseline, PASI75 response occurred more frequently in the CZP groups at weeks 12 and 24 compared to placebo.

In RAPID-PsA adverse events occurred in 62% vs. 68% and serious adverse events in 7% vs. 4% in certolizumab pegol (combined dose) vs. placebo, respectively. The most common adverse events with >5% incidence in both certolizumab pegol dosing arms or placebo were nasopharyngitis and upper respiratory tract infections. The most common serious adverse events in both certolizumab pegol dosing arms or placebo groups were infections and infestations (1.2% in the certolizumab pegol combined group vs. 0.7% in the placebo group).

Certolizumab pegol is not approved in the indication of psoriatic arthritis. UCB has filed certolizumab pegol in this indication with global regulatory authorities.

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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, leucopaenia (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 (including 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 andinactive (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 RAPID™-PsA

The RAPID™-PsA study is an ongoing 158 week study that was double-blind and placebo controlled to week 24, dose-blind to week 48 and open label to week 158. The study randomized 409 patients (1:1:1) with active psoriatic arthritis to receive either certolizumab pegol 200 mg every 2 weeks or 400 mg every 4 weeks or placebo. In the certolizumab pegol arms, patients received a loading dose of 400 mg certolizumab pegol at weeks 0, 2 and 4. Patients enrolled in this study must have failed at least one prior disease-modifying anti-rheumatic drug (DMARD). Patients in the study could have received one previous anti-TNF, provided they were not primary non-responders, as determined by the investigator. At baseline, approximately 19% of patients had previously failed one anti-TNF. Within the placebo arm, patients who did not respond to treatment (response defined as ≥10% decrease in tender joint count and swollen joint count) at weeks 14 and 16 were re-randomized at Week 16 to receive certolizumab pegol 200 mg every 2 weeks or 400 mg every 4 weeks following the loading dose.¹

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 9000 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2012. 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.