RAPID™-PsA study showed that certolizumab pegol improved the signs and symptoms of psoriatic arthritis vs. placebo

- ACR20 data from the RAPID™-PsA study presented at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Berlin, Germany, June 6-9, 2012

Slough, UK, 7th June 2012 – Results from the RAPID™-PsA study presented this week at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Germany showed that certolizumab pegol compared to placebo improved the signs and symptoms of arthritis in adult patients with active psoriatic arthritis (PsA).¹

"The RAPID™-PsA study is the first controlled study to assess the efficacy and safety of certolizumab pegol in adult patients with psoriatic arthritis," said Dr Philip J Mease, Director Rheumatology Research, Swedish Medical Center and University of Washington School of Medicine, Seattle, WA, USA. “Results from the study showed that certolizumab pegol improved the signs and symptoms of psoriatic arthritis when compared to placebo."²

The RAPID™-PsA study randomized 409 adult patients with established 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 disease-modifying anti-rheumatic drug (DMARD) and could have received a maximum of one anti-TNF (tumour necrosis factor). At baseline, 20% of patients had previously failed one anti-TNF. Within the placebo arm, patients who failed to achieve a ≥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

The primary endpoints of the study were the ACR20 response at week 12 and the modified total sharp score (mTSS) at week 24*. At week 12, the ACR20 response was significantly higher in both certolizumab pegol arms versus placebo (58.0%, 51.9%, vs. 24.3% in 200 mg, 400 mg and placebo respectively, p<0.001).¹

The most common adverse events with >5% incidence in the combined certolizumab pegol or placebo group were nasopharyngitis and upper respiratory tract infections. The most common serious adverse events with >1% incidence in the combined certolizumab pegol or placebo group were infections and infestations.²

In the European Union, certolizumab pegol in combination with methotrexate (MTX) is approved for the treatment of moderate to severe active RA in adult patients inadequately responsive to DMARDs including MTX. Certolizumab pegol can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Certolizumab pegol is not approved in the indication of psoriatic arthritis. UCB intends to file certolizumab pegol in this indication with global regulatory authorities by the end of 2012.

*Results from the primary endpoint assessing mTSS will be presented at a future congress
Psoriatic arthritis (PsA) is a condition involving joint inflammation (arthritis) that usually occurs in combination with a skin disorder called psoriasis. Signs and symptoms of PsA include stiff, painful joints with warmth and swelling in the joints and surrounding tissues. In the UK it is estimated that PsA affects approximately 0.1% to 0.3% of the total population in England and Wales, equating to 50,000 – 156,000 people. Between 5-7% of the psoriasis patient population has psoriatic arthritis with the propensity of this increasing to 40% in those with severe psoriasis.

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.


References

2. UCB Data on file


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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 8 500 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.