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## *Press Release*

### **UCB Provides Update on CIMZIA™ for Crohn's Disease and Rheumatoid Arthritis in the US**

UCB to initiate additional short-term clinical study in Crohn's disease

UCB to file in rheumatoid arthritis by year end 2007

**Brussels, Belgium, March 23, 2007 at 07:00 AM CET** – UCB has decided to initiate an additional short-term clinical study of CIMZIA™ (certolizumab pegol) to confirm the induction of clinical response in moderate to severe active Crohn's disease. UCB will work closely with the Food and Drug Administration (FDA) to finalise the design of the clinical study in order to provide additional clinical efficacy data. Furthermore, by end of April 2007 UCB will also reply fully to the Complete Response Letter received in December 21, 2006. In its Complete Response Letter, the FDA raised no major issues or concerns around the safety of CIMZIA™ or relating to Chemistry, Manufacturing and Controls (CMC) but did question the adequacy of one study design. UCB expects the results from this additional clinical study with CIMZIA™ in Crohn's disease in the second half of 2008.

The initial CIMZIA™ development programme for the treatment of Crohn's disease met all primary endpoints with statistical significance. Therefore, whether this additional study, which was not part of the pivotal trials program initially agreed with the FDA, will be a pre-approval requirement or a post-approval commitment, is still the subject of the ongoing communications with the FDA.

UCB plans to file a Biologics License Application (BLA) with the FDA for CIMZIA™ in the treatment of rheumatoid arthritis by year end 2007.

“We have complete confidence in CIMZIA™'s robust efficacy and competitive safety”, commented Roch Doliveux, Chief Executive Officer, UCB, “CIMZIA™ will be, at launch, the first anti-TNF which is a PEGylated and Fc-free antibody fragment. We are looking forward to making this new treatment option available to patients who suffer from rheumatoid arthritis and Crohn's disease, and will continue our dialogue with the FDA in order to obtain approval for CIMZIA™ in the US as soon as possible”.

### **Notes to the Editor**

For **CIMZIA™** in the treatment of **Crohn's disease**, UCB also applied for a marketing authorisation by the EMEA in April 2006 and anticipates launch in Europe at the end of 2007. In June 2005, UCB announced significant positive results for the two pivotal phase III trials (PRECiSE 1 and 2) of CIMZIA™ in the induction and maintenance of clinical response in moderate to severe active Crohn's disease. The primary endpoints in both the PRECiSE 1 and PRECiSE 2 trials were met with statistical significance.

**CIMZIA™** in the treatment of **rheumatoid arthritis** showed positive Phase III results demonstrating significant improvement in signs and symptoms and significant reduction in joint damage supported by strong radiographic data. Both phase III studies, RAPID 1 (027) and RAPID 2 (050), met their primary and co-primary endpoints with statistical significance.

The phase II trial (040) of **CIMZIA™** in **psoriasis** has demonstrated strong efficacy in this twelve-week study in the treatment of moderate to severe chronic plaque psoriasis. A retreatment study (044) is ongoing with results expected in the third quarter of 2007.

### **About Crohn's disease**

Crohn's disease is a chronic and debilitating inflammatory disease of the gastrointestinal tract, most commonly affecting the end of the small intestine (the ileum) and beginning of the large intestine (the colon). Together with ulcerative colitis, Crohn's disease belongs to the group of illnesses known as inflammatory bowel disease. Crohn's disease affects nearly one million people worldwide including an estimated 500,000 people in the United States. People with Crohn's disease may suffer an ongoing cycle of “flare-up” and remission. Symptoms of the disease include persistent diarrhoea, abdominal pain, and loss of appetite/weight, fever or rectal bleeding.<sup>3</sup> In an effort to provide Crohn's disease patients with disease management information and resources designed expressly with their needs in mind, UCB has launched *CrohnsAndMe.com* — a dynamic, cutting-edge web site focused on helping patients thoroughly understand Crohn's disease and live with it every day.

## **About CIMZIA™ (certolizumab pegol)**

CIMZIA™ (certolizumab pegol) is an investigational drug product. CIMZIA™ is the first and only PEGylated anti-TNF (Tumour Necrosis Factor) antibody. CIMZIA™ retains the potency of the original antibody without the possible cytotoxicity mediated by the Fc portion present in conventional anti-TNFs.

CIMZIA™ has a high affinity for human TNF-alpha, selectively targeting TNF-alpha in inflamed tissue. 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.

## **About UCB**

Headquartered in Brussels (Belgium), UCB ([www.ucb-group.com](http://www.ucb-group.com)) is a leading global biopharmaceutical company dedicated to the research, development and commercialisation of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology - UCB focuses on securing a leading position in severe disease categories. Employing more than 8400 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange and owns 87.6% of Schwarz Pharma.

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### **Forward-Looking Statement**

This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the safety, efficacy and potential benefits of certolizumab pegol, the development and commercialization of certolizumab pegol. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: the results of research, development and clinical trials; the timing and success of submission, acceptance, and approval of regulatory filings; the time and resources UCB devotes to the development and commercialization of certolizumab pegol and the scope of UCB's patents and the patents of others.