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## ***Press Release***

### **UCB Submits Marketing Authorisation Application in Europe for CIMZIA™, a New Crohn's Disease Therapy**

*First European submission of a subcutaneously-administered anti-TNF for the  
treatment of Crohn's disease*

**BRUSSELS (Belgium), April 28, 2006** - UCB today announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for the approval of CIMZIA™ (certolizumab pegol, CDP870) in the treatment of patients with Crohn's disease. When approved, CIMZIA™ will represent the first and only biologic administered by monthly subcutaneous injection as a treatment for Crohn's disease patients.

The European submission follows the filing of a Biologics License Application (BLA) for CIMZIA™ to the United States Food and Drug Administration (FDA) on March 1, 2006.

"As a leading European biopharmaceutical company, today's submission to the EMA is an important milestone for UCB, and underscores our commitment to providing a highly effective therapy for patients living with the burden of Crohn's disease," said Olav Hellebo, President of Inflammation Operations for UCB. "With the European MAA filing following closely behind our recent BLA filing to the FDA, the CIMZIA™ development programme is firmly on course. We also continue to explore other indications in the inflammation area for this promising biologic."

The European submission is based on safety and efficacy data from over 1,500 patients with Crohn's disease. The two pivotal phase III studies (PRECiSE 1 and PRECiSE 2) that support the MAA submission met their primary endpoints with

statistical significance, demonstrating CIMZIA™'s sustained and consistent efficacy in patients with Crohn's disease. The CIMZIA™ MAA submission represents the largest biologic clinical trial database submitted to the EMEA for Crohn's disease treatment. The PRECiSE studies also represent the broadest clinical trial programme, in terms of patient type, in Crohn's disease, encompassing patients with previous exposure to an anti-TNF treatment with a range of concomitant therapies and variable duration of disease.

"The results we have seen in the PRECiSE studies have been highly encouraging, suggesting CIMZIA™ to be well-tolerated and effective in the treatment and maintenance of response and remission in patients with Crohn's disease," commented Professor Stefan Schreiber, Professor of Medicine and Gastroenterology at the Christian-Albrechts University, Kiel, Germany, and a leading investigator in the CIMZIA™ clinical trials program. "In addition, CIMZIA™ when approved will offer the convenience of monthly dosing, combined with a patient-friendly subcutaneous route of administration."

"With Crohn's disease affecting almost half a million people in Europe, the unmet needs of these patients are significant," said Prof. Paul Rutgeerts, Professor of Medicine at the Katholieke Universiteit Leuven, Belgium. "There is a definite need for new therapies, allowing physicians more options for providing effective long-term relief from the significant burden of this debilitating disease."

In addition to the current development programme in Crohn's disease, ongoing studies are investigating the efficacy and tolerability of CIMZIA™ in the treatment of rheumatoid arthritis and psoriasis.

### **About CIMZIA™**

CIMZIA™ is the first and only PEGylated Fab' fragment of a humanized anti-TNF-alpha antibody (TNF - Tumour Necrosis Factor). The engineered Fab' fragment retains the biologic potency of the original antibody. 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.

### **About the PRECiSE Program**

Data from PRECiSE 2 demonstrated that within six weeks of initiating CIMZIA™, 64.1 percent of patients (428 of 668) achieved a clinical response as defined by greater than or equal to 100 point reduction in the Crohn's Disease Activity Index (CDAI) score (a composite score of eight factors used to assess a patient's wellness). Responders were randomized to CIMZIA™ 400 mg or placebo every four weeks. At the end of 26 weeks, significantly more patients, 62.8 percent (135 of 215) on CIMZIA™ vs. 36.2 percent (76 of 210) on placebo, maintained an overall clinical response. Additionally, at 26 weeks, significantly more of CIMZIA™ patients were in clinical remission (CDAI  $\leq$ 150 points) compared to placebo patients, 47.9 percent (103 of 215) vs. 28.6 percent (60 of 210), respectively. CIMZIA™ was generally well tolerated with an adverse event profile similar to other anti-TNF agents. The PRECiSE clinical program is composed of four studies (PRECiSE 1, 2, 3, and 4). PRECiSE 3 and 4 are both 24-month open-label trials assessing the longer-term safety and tolerability of CIMZIA™ and are currently ongoing.

**NOTE TO EDITOR: PRECiSE 2 data were presented at both the 2005 United European Gastroenterology Week and American College of Gastroenterology medical meetings<sup>1</sup>. PRECiSE 1 data will be presented at Digestive Disease Week (20-25 May 2006, Los Angeles, CA).**

### **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 and an estimated 500,000 people in Europe. 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>2</sup>.

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<sup>1</sup> Schreiber *et al.* Certolizumab pegol, a humanised anti-TNF PEGylated Fab' fragment is safe and effective in the maintenance of response and remission following induction in active Crohn's disease: a Phase III study (PRECiSE). *Gut* 2005; 54 (Suppl VII) A82.

<sup>2</sup> Source: Crohn's and Colitis Foundation of America. Disease Information page: <http://www.cdfa.org/info/about/crohns> Accessed April 7, 2006.

## **About UCB**

UCB ([www.ucb-group.com](http://www.ucb-group.com)) is a leading global biopharmaceutical company dedicated to the research, development and commercialization 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 over 8,500 people in over 40 countries, UCB achieved revenues of € 2.3 billion in 2005. UCB is listed on the Euronext Brussels Exchange with a market capitalization of approximately € 6.0 billion. Worldwide headquarters are located in Brussels, Belgium.

## **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. In addition, the statements in this press release represent UCB's expectations and beliefs as of the date of this press release. UCB anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while UCB may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing UCB's expectations or beliefs as of any date subsequent to the date of this press release.

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