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## ***Press Release***

### **UCB Submits Biologics License Application to FDA for New Treatment in Crohn's Disease**

*CIMZIA™ submission represents a major step towards the approval of  
the first ever subcutaneous treatment for Crohn's disease*

**BRUSSELS (Belgium) and ATLANTA, Georgia (USA), March 2, 2006** — UCB announced today the submission of a Biologics License Application (BLA) to the United States Food and Drug Administration (FDA) for the approval of CIMZIA™ (certolizumab pegol, CDP870) for the treatment of patients with Crohn's disease. If approved, CIMZIA™ would be the first-ever biologic utilizing subcutaneous injection for the treatment of Crohn's disease.

"Our BLA submission is an important milestone for UCB; it represents the tremendous efforts of UCB's CIMZIA™ development team, and marks UCB's entry into the biologics market," said Roch Doliveux, CEO and Chairman of the Executive Committee for UCB. "We plan to request marketing authorization from the European Agency for the Evaluation of Medicinal Products (EMA) in a matter of weeks. UCB is also continuing its research and development work to explore additional auto-immune diseases for this promising biologic."

The BLA includes safety and efficacy data from well-controlled clinical trials in more than 1,500 patients with Crohn's disease. The pivotal studies (PRECiSE 1 and PRECiSE 2) that support the BLA submission met their primary endpoints by demonstrating that CIMZIA™ induced clinical response and maintained clinical response and remission in a significant percentage of patients with Crohn's disease.

The CIMZIA™ BLA package represents the largest biologic clinical trial database and broadest, in terms of patient types, submitted to the FDA for Crohn's disease treatment.

“There are significant unmet needs among Crohn's patients, so additional therapeutic agents will increase our ability to provide effective long-term relief from this debilitating disease,” commented William Sandborn, M.D., Professor of Medicine at the Mayo Clinic College of Medicine and a leading investigator in the CIMZIA™ clinical trial program. “Our experience in the PRECiSE clinical trials program has shown CIMZIA™ to be a well-tolerated and effective treatment. In addition, subcutaneous administration is a welcomed attribute for patients and can offer greater convenience.”

In addition to the completed and ongoing studies in Crohn's disease, CIMZIA™ studies are also ongoing 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 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 production has been directly implicated in a wide variety of diseases.

#### **About PRECiSE Program**

Data from PRECiSE 2, presented in October 2005 at the United European Gastroenterology Week, 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.

### **About Crohn's Disease**

Crohn's disease, a chronic and debilitating inflammatory disease of the gastrointestinal tract, affects nearly one million patients worldwide and 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 vary among people, but include persistent diarrhea, abdominal pain, and loss of appetite/weight, fever or rectal bleeding.<sup>1</sup>

**NOTE TO EDITOR: PRECiSE 2 data were presented at both the 2005 American College of Gastroenterology and United European Gastroenterology Week medical meetings. PRECiSE 1 data will be presented at major medical meetings in 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 € 2.1 billion in 2004. UCB is listed on the Euronext Brussels Exchange with a market capitalization of approximately € 5.8 billion. Worldwide headquarters are located in Brussels, Belgium, and U.S. headquarters are located in Atlanta, Georgia.

### **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.

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<sup>1</sup> Source: Crohn's and Colitis Foundation of America. Disease Information page: [www.cffa.org/info/about/crohns](http://www.cffa.org/info/about/crohns) Accessed January 26, 2006

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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