



UCB S.A. 60 Allée de la Recherche, B-1070 Brussels (Belgium)

## *Press Release*

### **UCB Presents Long-Term CIMZIA™ Data in Crohn's Disease**

*CIMZIA™ maintained long-term response at stable doses,  
according to new data presented at Digestive Disease Week (DDW)*

**Brussels, Belgium, May 22, 2007 at 7:00 AM (CET)** — UCB announced today that new data presented at Digestive Disease Week 2007 (DDW) demonstrated long-term response and remission in Crohn's disease patients treated with CIMZIA™ (certolizumab pegol), the only Fc-free PEGylated, Fab' fragment anti-TNF.

The study, called PRECiSE 3 (P3), is a long-term open label continuation of the Phase III PRECiSE Program for CIMZIA™. Some of the study results presented at DDW are an interim analysis of a patient subgroup who responded continuously to CIMZIA™ during an 18-month period. These patients completed the PRECiSE 1 (P1) or PRECiSE 2 (P2) trials, enrolling in P3 at week 52. At week 80, the study showed that more than 85 percent of the patient subgroup who continuously received CIMZIA™ 400 mg subcutaneously every four weeks maintained clinical response, with nearly 74 percent of these patients achieving remission.<sup>1</sup> The extension study used the Harvey-Bradshaw Index (HBI)<sup>3</sup> to assess clinical response (defined as a reduction in HBI score of at least three points) and remission (HBI score less than or equal to four points).

Importantly, results reported from P3 indicated that CIMZIA™ was well-tolerated throughout the study. The percentage of patients experiencing injection-site reactions and injection-site pain was low (<2%, <1% respectively).<sup>3</sup>

"These study results show robust rates of clinical response and remission during an 18-month period in patients with Crohn's disease," said Stephen Hanauer, M.D., Professor of Medicine and Clinical Pharmacology Chief, Section of Gastroenterology and Nutrition, University of Chicago, and study co-author. "Also, CIMZIA™ dosing did not need to be increased over the course of the study."

"These results fortify UCB's commitment to obtain regulatory approval for CIMZIA™ in the treatment of Crohn's disease. They help demonstrate the benefits CIMZIA™, administered subcutaneously every four weeks, can offer to those suffering from this debilitating condition," commented Olav Hellebo, Senior Vice President and President of Inflammation Operations, UCB.

### **PRECiSE 3 Study Design**

CIMZIA™ was administered subcutaneously every four weeks at stable doses of 400 mg, with an induction dose at weeks 0, 2 and 4. The patients represented a broad population living with moderate to severe Crohn's disease, including patients who had previously received infliximab, another biologic for the treatment of Crohn's, those treated with monotherapy, or those treated with immunosuppressants.

P3 is an open-label extension study that recruited a total of 595 patients from the placebo-controlled studies P1 and P2. Group A (329 patients) responded to treatment and completed the P1 and P2 clinical trials. Upon completion, the patients enrolled in P3. Group B (99 patients) responded to induction therapy with CIMZIA™ in P2 at Weeks 0, 2 and 4, and were randomized to placebo in P2 and then enrolled in P3. Groups A and B received CIMZIA™ in the P3 study.

The primary endpoint of P3 was to assess the safety of chronic therapy with CIMZIA™. The secondary endpoints were to obtain data on plasma concentrations and antibodies to CIMZIA™ and to obtain additional efficacy data with up to 18 months continuous exposure to CIMZIA™.

For patients with continuous exposure to CIMZIA™ during P1 and P2 (Group A), at week 52, 78.8 percent (204/259 patients) maintained clinical response and 65.6 percent (170/259 patients) maintained remission as measured by a reduction in HBI score of at least three points and a remission HBI score of less than or equal to four. At week 80, response and remission was maintained by 85.8 percent (182/212 patients) and 73.6 percent (156/212 patients), respectively. Patients who were randomized to placebo in P1 or P2 (Group B) and who began treatment again in P3, maintained response and remission by 86.8 percent (59/68 patients) and 75 percent (51/68 patients), respectively, at week 80. Patients who did not complete or withdrew from P3 were counted as non-responders and were not included in this analysis.

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

CIMZIA™ is an investigational drug product. CIMZIA™ is the only Fc-free PEGylated Fab' fragment anti-TNF (Tumour Necrosis Factor). CIMZIA™ is Fc-free and thus avoids potential cellular cytotoxicity. 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.

UCB filed a BLA with the Food and Drug Administration (FDA) for CIMZIA™ in the treatment of Crohn's disease on February 28, 2006 and on April 28, 2006 submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the same indication.

Also, recent study results (RAPID 1 and RAPID 2) have demonstrated CIMZIA™'s clinical efficacy and tolerability in rheumatoid arthritis.<sup>4</sup> UCB plans to file for the treatment of rheumatoid arthritis with regulatory agencies in the U.S. and Europe.

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

Crohn's disease is a chronic disorder that causes inflammation of the gastrointestinal (GI) tract, most commonly at the end of the small intestine (the ileum) and in the large intestine (the colon). People with Crohn's disease may suffer all of their lives, experiencing an ongoing cycle of "flare-up" and remission. Together with ulcerative colitis, Crohn's disease is an inflammatory bowel disease (IBD).<sup>5</sup>

### ***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 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 more than 8,400 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.

### ***About DDW***

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 19-24, 2007, at the Washington Convention Center, Washington, DC. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit [www.ddw.org](http://www.ddw.org).

**Enquiries, please contact:**

<b>Investor Relations</b>	<b>International Media</b>	<b>US Media</b>
Jean-Christophe Donck, UCB Phone: +32 2 559 9346 E-mail: <a href="mailto:JC.Donck@ucb-group.com">JC.Donck@ucb-group.com</a>	Garry Daniels, UCB Phone : +44 1753 777 116 E-mail: <a href="mailto:garry.daniels@ucb-group.com">garry.daniels@ucb-group.com</a>  Nina Jones Fleishman-Hillard Phone: +44 7395 7143 E-mail: <a href="mailto:jonesni@fleishmaneuropa.com">jonesni@fleishmaneuropa.com</a>	Lisa Garman, UCB, Inc. Phone: +1-770-970-8569 E-mail: <a href="mailto:lisa.garman@ucb-group.com">lisa.garman@ucb-group.com</a>  Kathryn Mayurnik Fleishman-Hillard Phone: +1-212-453-2409 E-mail: <a href="mailto:kathryn.mayurnik@fleishman.com">kathryn.mayurnik@fleishman.com</a>

<sup>a</sup> Harvey-Bradshaw Index (HBI) and Crohn's Disease Activity Index (CDAI): Crohn's disease activity can be measured using two types of indices; Crohn's Disease Activity Index (CDAI) and the Harvey-Bradshaw Index (HBI), they are both particularly important for use in research trials as they demonstrate how effective treatments are at controlling Crohn's disease. CDAI is used to quantify the severity of Crohn's disease using symptom scores that are monitored over one week. The HBI is a simple measurement of Crohn's disease activity over a 24 hour period, and a simpler version of the CDAI as it consists of clinical parameters only. HBI is a simple and easy to use measure for CD activity that may be used as an alternative to CDAI.<sup>2</sup>

**References**

<sup>1</sup> Schreiber S et al. Long-term treatment with certolizumab pegol for up to 18 months in patients with active Crohn's disease: PRECiSE 3 efficacy results. Poster presentation at DDW 2007, Washington DC.

<sup>2</sup> Vermeire S et al. Determination of Harvey-Bradshaw Index (HBI) definitions for response and remission using the CDAI data from PRECiSE 1 and PRECiSE 2. Poster at DDW 2007, Washington DC.

<sup>3</sup> Colombel JF et al. Long-term tolerability of subcutaneous certolizumab pegol in active Crohn's disease: results from PRECiSE 3 and 4. Poster presentation at DDW 2007, Washington DC.

<sup>4</sup> Data on file.

<sup>5</sup> Crohn's and Colitis Foundation of America. Disease Information page ([www.cdfa.org/info/about/crohns](http://www.cdfa.org/info/about/crohns) accessed on 8 May 2007).