



Press Release - Regulated information

## **Cimzia® Approved in the US for the Treatment of Moderate to Severe Crohn's Disease**

**Administered every four weeks, UCB's pegylated anti-TNF $\alpha$  offers new treatment option for patients with moderate to severe Crohn's disease.**

**Cimzia® will be available in the US within the next 48 hours.**

**Brussels (Belgium) – April 22, 2008 - 19.30 CET** — UCB announced today that the US Food and Drug Administration (FDA) has approved Cimzia® (certolizumab pegol), the first and only PEGylated anti-TNF $\alpha$  (Tumor Necrosis Factor alpha) antibody indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have an inadequate response to conventional therapy.

"The approval of Cimzia® in the United States is a significant milestone for both UCB and our Cimzia® team, but especially for people suffering from Crohn's disease," said Roch Doliveux, Chief Executive Officer of UCB Group. "Cimzia® is a UCB biological innovation that will provide a monthly treatment option for patients suffering from Crohn's disease. Cimzia® will be available to doctors and Crohn's patients in the United States, which represents 70% of the world Crohn's anti-TNF market, within the next 48 hours."

The approval of Cimzia® was based on safety and efficacy data from clinical trials in more than 1 500 patients with Crohn's disease. Each pivotal study demonstrated that a statistically significant greater proportion of moderate to severe Crohn's disease patients achieved and sustained clinical response with Cimzia® for up to six months, compared to placebo. These data also showed that of the patients who were in remission after initial dosing, the majority maintained remission with no dose escalation.

Cimzia® is the first and only PEGylated anti-TNF $\alpha$ . Cimzia® is dosed subcutaneously every four weeks after initial dosing, making it a convenient option for people with moderate to severe Crohn's. Cimzia® has demonstrated a low incidence of injection site reactions and injection site pain in clinical trials. The most common reported adverse events in the pivotal studies were upper respiratory tract infection (cold, flu), urinary tract infection (bladder infection) and joint pain. As seen with the use of the other anti-TNF $\alpha$  agents, serious, but infrequent infections and malignancies have been reported.

"The clinical trials program has shown Cimzia® to be an effective subcutaneously-administered treatment, with a low rate of injection site reactions," said Stephen Hanauer, M.D., Professor of Medicine and Clinical Pharmacology at the University of Chicago. "The approval of Cimzia® provides a new option for people with Crohn's disease to achieve relief from this debilitating condition with a convenient, stable administration once every four weeks."



### **About Cimzia® (certolizumab pegol)**

*Cimzia® is the first and only PEGylated anti-TNF $\alpha$  (Tumor Necrosis Factor alpha). 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 is developing Cimzia® in Crohn's Disease, RA and other autoimmune disease indications. For additional information, including safety information, please refer to the Cimzia® factsheet in the "News" section of UCB's website ([www.ucb-group.com](http://www.ucb-group.com)).*

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

*Crohn's disease is a chronic, progressive, destructive disorder that causes inflammation of the gastrointestinal (GI) tract, most commonly at the end of the small intestine (the ileum) and beginning of the large intestine (the colon). If not effectively treated, it results in the need for surgery. Crohn's disease has been estimated to affect as many as half a million Americans. People with Crohn's can experience an ongoing cycle of flare-up and remission throughout their lives. Together with ulcerative colitis, Crohn's disease is an inflammatory bowel disease (IBD).*

### **About UCB**

*UCB (Brussels, Belgium) ([www.ucb-group.com](http://www.ucb-group.com)) is a global leader in the biopharmaceutical industry 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 around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion euro in 2007. UCB S.A. is listed on Euronext Brussels.*

### **Further information**

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### **Forward looking statement**

*This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.*