



## **NEWLY-APPROVED CIMZIA<sup>®</sup> PROVIDES RAPID, SUSTAINED RESPONSE IN CROHN'S PATIENTS**

**Data from WELCOME Study Presented at Digestive Disease Week (DDW) 2008, San Diego, CA. (USA)**

**San Diego – May 20, 2008 at 8:45 a.m. PT** – UCB today presented data at the Digestive Disease Week meeting that showed Cimzia<sup>®</sup> (certolizumab pegol) provided an effective and rapid clinical response in more than 60 percent of Crohn's disease patients who were intolerant, or no longer responding to infliximab. Over 39 percent of patients achieved remission by six weeks. Data also showed one-third of patients responded after receiving only the initial dose. [Abstract #494]

"Data from the UCB clinical trials program including the WELCOME and PRECiSE studies has demonstrated that certolizumab pegol is effective in inducing and sustaining clinical response in a broad range of patients with moderate to severe Crohn's disease," said David G. Binion, M.D., director, IBD Center and professor of medicine at the Medical College of Wisconsin in Milwaukee, Wis. "The addition of Cimzia<sup>®</sup> into our pharmacologic armamentarium to control chronic intestinal inflammation is an important advance for patients who suffer from Crohn's disease."

Cimzia<sup>®</sup> is the first and only PEGylated anti-TNF $\alpha$  (Tumor Necrosis Factor alpha) antibody approved 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. Cimzia<sup>®</sup>, manufactured by UCB, was approved by the U.S. Food and Drug Administration (FDA) on April 22, 2008. The approval was based on safety and efficacy data from clinical trials in more than 1,500 patients with Crohn's disease.

The response rates in this study, measured by a decrease ( $\geq 100$  points from baseline) in the Crohn's Disease Activity Index (CDAI) score, were comparable to those in an earlier study, the PRECiSE 2 trial, where 64 percent of patients in the overall population achieved response to Cimzia<sup>®</sup>.

Cimzia<sup>®</sup> was consistently effective across all patient groups, demonstrating similar results in patients who were and were not receiving concomitant immunosuppressants or steroids. The most common adverse events were headache, nasopharyngitis, nausea, vomiting, pyrexia and arthralgia. The incidence of serious adverse events (SAEs) was seven percent and the most frequent SAEs involved gastrointestinal disorders (five percent) and infections and infestations (2 percent). No unexpected safety concerns were identified during this study.



### **About WELCOME**

The WELCOME study is a 539 patient Phase IIIb multicenter 26-Week trial Evaluating the clinical benefit and tolerability of certoLizumab pegol induCtiOn and Maintenance in patients suffering from Crohn's disease with prior loss of response or intolerEance to infliximab. It consists of an open-label induction phase (400 mg of Cimzia® sub-cutaneously at Weeks 0, 2 and 4) and a double-blind maintenance period (400 mg of Cimzia® every 2 or 4 weeks from Week 6). The primary endpoint was defined as the rate of response (defined as a decrease in CDAI score  $\geq 100$  points from baseline) at Week 6. Remission was defined as a CDAI score of  $\leq 150$  points. After the induction period, 62.2 percent of patients achieved response and 39.3 percent achieved remission. One-third of patients had responded to treatment by Week 2 (33.2 percent) and more than forty percent (43.8 percent) had responded by Week 4.

### **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 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, rheumatoid arthritis and other autoimmune disease indications. Cimzia® is a registered trademark of UCB Inc. For full prescribing information, please visit [www.Cimzia.com](http://www.Cimzia.com).

### **IMPORTANT SAFETY INFORMATION**

Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections, have been observed in patients receiving Cimzia®. Some of these infections have been fatal. Anti-tuberculosis treatment of patients with latent tuberculosis infection reduces the risk of reactivation in patients receiving treatment with TNF blockers such as Cimzia®. However, active tuberculosis has developed in patients receiving Cimzia® whose tuberculin test was negative. Evaluate patients for tuberculosis risk factors and test for latent tuberculosis infection prior to initiating Cimzia® and during therapy. Initiate treatment of latent tuberculosis infection prior to therapy with Cimzia®. Monitor patients receiving Cimzia® for signs and symptoms of active tuberculosis, including patients who tested negative for latent tuberculosis infection. Consider anti-tuberculosis therapy prior to initiation of Cimzia® in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed.



Serious infections, sepsis, and cases of opportunistic infections, including fatalities, have been reported in patients receiving TNF blockers, including Cimzia<sup>®</sup>. Infections have been reported in patients receiving Cimzia<sup>®</sup> alone or in conjunction with immunosuppressive agents. Do not initiate treatment with Cimzia<sup>®</sup> in patients with active infections, including chronic or localized infections. Patients who develop a new infection while undergoing treatment with Cimzia<sup>®</sup> should be monitored closely. Discontinue administration of Cimzia<sup>®</sup> if a patient develops a serious infection. Exercise caution when considering the use of Cimzia<sup>®</sup> in patients with a history of recurrent infection, concomitant immunosuppressive therapy, or underlying conditions that may predispose them to infections, or patients who have resided in regions where tuberculosis and histoplasmosis are endemic.

Use of TNF blockers, including Cimzia<sup>®</sup>, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating Cimzia<sup>®</sup> therapy. Exercise caution in prescribing Cimzia<sup>®</sup> for patients identified as carriers of HBV. Patients who are carriers of HBV and require treatment with Cimzia<sup>®</sup> should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy. In patients who develop HBV reactivation, discontinue Cimzia<sup>®</sup> and initiate effective anti-viral therapy with appropriate supportive treatment.

During controlled and open-labeled portions of Cimzia<sup>®</sup> studies of Crohn's disease and other investigational uses, malignancies were observed at a rate (95% confidence interval) of 0.6 (0.4, 0.8) per 100 patient-years among 4,650 Cimzia<sup>®</sup>-treated patients versus a rate of 0.6 (0.2, 1.7) per 100 patient-years among 1,319 placebo-treated patients. The size of the control group and limited duration of the controlled portions of the studies preclude the ability to draw firm conclusions. In studies of Cimzia<sup>®</sup> for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 Cimzia<sup>®</sup>-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. The potential role of TNF blocker therapy in the development of malignancies is not known.

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following Cimzia<sup>®</sup> administration. If such reactions occur, discontinue further administration of Cimzia<sup>®</sup> and institute appropriate therapy.

Use of TNF blockers, including Cimzia<sup>®</sup>, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with Cimzia<sup>®</sup>; the causal relationship to Cimzia<sup>®</sup> remains unclear. Exercise caution in considering the use of Cimzia<sup>®</sup> in patients with these disorders.



Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently reported with Cimzia<sup>®</sup>. The causal relationship of these events to Cimzia<sup>®</sup> remains unclear. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia<sup>®</sup>. Consider discontinuation of Cimzia<sup>®</sup> therapy in patients with confirmed significant hematologic abnormalities.

Serious infections were seen in clinical studies with concurrent use of anakinra (an interleukin-1 antagonist) and another TNF blocker, with no added benefit. Therefore, the combination of Cimzia<sup>®</sup> and anakinra is not recommended.

Interference with certain coagulation assays has been detected in patients treated with Cimzia<sup>®</sup>. There is no evidence that Cimzia<sup>®</sup> therapy has an effect on *in vivo* coagulation.

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Cimzia<sup>®</sup> has not been formally studied in patients with CHF. Exercise caution when using Cimzia<sup>®</sup> in patients who have heart failure and monitor them carefully.

Treatment with Cimzia<sup>®</sup> may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Do not administer live vaccines or attenuated vaccines concurrently with Cimzia<sup>®</sup>.

In controlled Crohn's clinical trials, the most common adverse events that occurred in  $\geq 5\%$  of Cimzia<sup>®</sup> patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% Cimzia<sup>®</sup>, 13% placebo), urinary tract infection (7% Cimzia<sup>®</sup>, 6% placebo), and arthralgia (6% Cimzia<sup>®</sup>, 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for Cimzia<sup>®</sup> and 7% for placebo.

Cimzia<sup>®</sup> should be administered by a healthcare professional.

#### **About Digestive Disease Week (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 17-22, 2008, at the San Diego Convention Center, San Diego, CA. 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).



### **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.

### **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.

### **Further Information**

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