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Press Release

New Efficacy Data Show CIMZIA™ (Certolizumab Pegol) Maintained Response and Remission in Crohn's Patients Previously Treated With Infliximab

BRUSSELS, BELGIUM, October 23, 2006 – 2:00 pm CET — New data from a post hoc analysis of the PRECiSE clinical trial program demonstrated that the anti-TNF CIMZIA™ (certolizumab pegol) maintained response and remission in patients with moderate to severe Crohn's disease, regardless of whether or not they had been previously treated with infliximab. These results build on the PRECiSE 2 study results previously presented, which showed that subcutaneous administration of CIMZIA™ (certolizumab pegol), given every four weeks with an additional induction dose at week 2, demonstrated a statistically significant rate of response and remission at week 26 compared to placebo in patients responding at Week 6. CIMZIA™ (certolizumab pegol) may offer an alternative to currently available therapies.

These new analyses will be presented this week at the 14th United European Gastroenterology Week (UEGW) in Berlin, Germany and the 2006 American College of Gastroenterology (ACG) Annual Scientific Meeting in Las Vegas, Nevada, USA.

"Physicians and patients appreciate new options when dealing with diseases and symptoms that can dramatically affect their daily lives, as is the case with patients suffering from Crohn's disease," said Stephen Hanauer, M.D., Professor of Medicine and Clinical Pharmacology Chief, Section of Gastroenterology and Nutrition, University of Chicago, USA, at the ACG. "The study reinforces that there is a clear need for new therapies such as CIMZIA, to provide patients with therapeutic options to better manage their disease and improve their quality of life."

The new data, to be presented at UEGW and ACG by Professors Colombel and Hanauer respectively, analyzed the efficacy and tolerability of CIMZIA™ (certolizumab pegol) in patients who had previously taken infliximab or not. Of those randomized at week 6, 68.7% of the infliximab-naïve patients and 44.2% of patients previously treated with infliximab achieved a clinical response, defined as ≥100 point decrease in Crohn's Disease Activity Index (CDAI)[1].

A similar pattern of results was observed for remission at week 26, based on a CDAI score[1] ≤ 150 points, as well as a 16 point or greater increase in the Inflammatory Bowel Disease Questionnaire[2] (IBDQ) score. These results were statistically significantly different from those observed with placebo. Additionally, no significant differences were observed between the two groups in terms of either overall adverse events or serious adverse events.

"It is important to determine whether a patient's prior exposure to infliximab will affect the safety or effectiveness of newer therapies with distinct mechanisms of action," said Professor Jean-Frederic Colombel, Department of Hepato-Gastroenterology, Claude Huriez Hospital, Lille, France at the UEGW meeting. "This new information suggests that CIMZIA may be an effective new option for treating Crohn's patients regardless of any previous infliximab treatment."

Rates of Response and Remission Demonstrated at Week 26

	Patients (%)			
	Infliximab-naive		**Prior infliximab**	
	Certolizumab pegol (n=163)	**3 doses followed by placebo (n=159)**	**Certolizumab pegol (n=52)**	**3 doses followed by placebo (n=51)**
Clinical Response†	68.7[a]	39.6	44.2[b]	25.5
Remission†	52.8[a]	33.3	32.7[c]	13.7
†Wk 26, Intention To Treat; p-values vs. placebo: [a]<0.001, [b] 0.018, [c]0.008.				

PRECiSE Clinical Trials Program

The PRECiSE Program, composed of four studies (PRECiSE 1, 2, 3, and 4), represents an innovative, large, comprehensive development program for CIMZIA™ (certolizumab pegol) in Crohn's disease, including over 1,300 patients, with a planned follow-up phase of up to five years.

PRECiSE 1 is a unique trial in patients with active Crohn's disease — the first reported Phase III double-blind, placebo-controlled study of an anti-TNF extending to 26 weeks, in which eligible patients were randomized at study baseline without pre-selection of responders. Both co-primary endpoints were met with statistical significance.[3]

In the previously reported **PRECiSE 2** study, patients responding at Week 6 to open-label induction therapy with CIMZIA™ (certolizumab pegol) were randomized to either placebo (n=210) or CIMZIA™ (certolizumab pegol) (n=215) and followed for a total of 26 weeks. In this trial, 62.8% of CIMZIA™ (certolizumab pegol) patients, compared to 36.2% of placebo patients, maintained clinical response at Week 26 ($p<0.001$). Clinical response was defined as a ≥100 point decrease in CDAI. Similarly, 47.9% of CIMZIA™ (certolizumab pegol) patients were in clinical remission at week 26 compared to 28.6% on placebo ($p<0.001$).[4] Remission was defined as CDAI $\leq$ 150 points.

Serious adverse events occurred in 5.6% of CIMZIA™ (certolizumab pegol) patients during the double blind phase. One case of tuberculosis, which responded well to anti-tuberculosis therapy, was observed in the CIMZIA™ (certolizumab pegol) arm of the PRECiSE 2 trial. Local injection reactions were low in PRECiSE 2 (2.8%), and less frequent than seen with placebo. The percentage of patients who tested positive for auto-antibody formation at Week 26 (and were negative at baseline) was only 8.3% for anti-nuclear antibodies and 1.0% for anti-double-stranded DNA antibodies in PRECiSE 2. No cases of lupus were reported.[4]

PRECiSE 3 and 4 are both long-term (up to five years) open-label trials assessing the longer-term efficacy, safety and tolerability of CIMZIA™ (certolizumab pegol) in patients from PRECiSE 1 and PRECiSE 2, and are currently ongoing.

New Studies Initiated

UCB continues to study the clinical profile of CIMZIA™ (certolizumab pegol) in Crohn's disease. Enrollment has commenced in a new clinical trial involving 600 patients called WELCOME. The study will further examine the effects of CIMZIA™ (certolizumab pegol) in patients failing or intolerant to infliximab. In addition, the MUSIC study will investigate the impact of CIMZIA™ (certolizumab pegol) on endoscopic and mucosal healing, and the CONCISE trial will examine the corticosteroid-sparing effect of CIMZIA™ (certolizumab pegol) in Crohn's disease.

About CIMZIA™ (certolizumab pegol)

UCB filed a BLA with the Food and Drug Administration (FDA) for CIMZIA™ (certolizumab pegol) in the treatment of Crohn's disease on February 28th, 2006 and on April 28, 2006 submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for the same indication. CIMZIA™ (certolizumab pegol) is the first and only PEGylated Fab' fragment of a humanized anti-TNF-alpha antibody (TNF-alpha; Tumour Necrosis Factor), evaluated as once-monthly dosing administered subcutaneously. The engineered Fab' fragment retains the biologic potency of the original antibody without the cytotoxicity mediated by the Fc portion present in the original monoclonal antibodies. CIMZIA™ (certolizumab pegol) 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 Crohn's Disease

Crohn's disease is a chronic, progressive 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, including an estimated 500,000 people in the United States and a further 500,000 people in Europe[4]. 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. Severe symptoms may result in the need for surgical intervention. In an effort to provide Crohn's disease patients with disease management information and resources designed expressly with their needs in mind, UCB has launched patient Web sites in the U.S (*CrohnsandMe.com)* and Europe *(CrohnsandMe.eu*). Both are dynamic, cutting-edge Web sites focused on helping patients thoroughly understand Crohn's disease and live with it every day.

About UCB

UCB (www.ucb-group.com <http://www.ucb-group.com>) is a leading global biopharmaceutical company dedicated to the research, development and commercialisation 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 8,300 people in over 40 countries, UCB achieved revenue of 2.3 billion euro in 2005. UCB is listed on the Euronext Brussels Exchange and its worldwide headquarters are located in Brussels, Belgium.

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[1] The CDAI score, or Crohn's Disease Activity Index, measures the severity of Crohn's disease by taking into account a number of factors such as intensity of symptoms, medication and general well-being. Patients with high scores have highly active Crohn's disease, while low scores indicate the disease is less active.

[2] Inflammatory Bowel Disease Questionnaire (IBDQ) assesses quality of life in patients with inflammatory bowel diseases.

[3] Sandborn WJ, Feagan BG, Stoinov S *et al*. Certolizumab pegol administered subcutaneously is effective and well tolerated in patients with active Crohn's disease: results from a 26-week, placebo-controlled Phase III study (PRECiSE 1). Presented at Digestive Disease Week, Los Angeles, California, USA, 23rd May 2006.

[4] Schreiber S 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.

[5] Source: Crohn's and Colitis Foundation of America. Disease Information page: http://www.ccfa.org/info/about/crohns Accessed October 3, 2006.