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Press Release

Phase III study shows CIMZIA™ is an effective and well-tolerated treatment for Crohn's disease

Copenhagen, Denmark, October 18, 2005 – UCB announced today at the United European Gastroenterology Week the detailed Phase III study results (PRECiSE 2) for CIMZIA™ (certolizumab pegol, CDP870) in the treatment of Crohn's disease. The results of the PRECiSE 2 study show that the anti-TNF CIMZIA was efficacious at decreasing or controlling the signs and symptoms of Crohn's disease. UCB's anti-TNF treatment, which is administered via subcutaneous injection, was also shown to be well-tolerated.[1] A regulatory submission for the treatment of Crohn's disease is scheduled to be filed for CIMZIA in both the US and Europe during the first quarter of 2006.

"We now have a potential treatment for Crohn's disease which has shown the efficacy expected of an anti-TNF but was well tolerated and offered the advantage of subcutaneous administration," explains Prof Stefan Schreiber, Principal Investigator for PRECiSE 2 and Professor of Medicine and Gastroenterology at the Christian-Albrechts University, Kiel. "For people suffering the life-altering and devastating symptoms of Crohn's disease, CIMZIA could enable them to effectively control their disease."

PRECiSE 2, a 26 week study in 668 patients, demonstrated that CIMZIA 400mg, administered every four weeks, maintained clinical response following induction therapy in moderate to severe Crohn's disease[1]. Clinical response was defined as at least a 100 point decrease in CDAI score.*

* 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.

After induction with CIMZIA at weeks 0, 2 and 4, the 428 patients who achieved a clinical response (64%) were randomised to either placebo or CIMZIA up to week 24. PRECiSE 2 showed that:

- 62.8% of patients receiving CIMZIA maintained an overall clinical response at week 26, compared to 36.2% receiving placebo ($p<0.001$)
- 47.9% of patients receiving CIMZIA were in clinical remission at week 26 compared to 28.6% receiving placebo ($p<0.001$)
- the primary endpoints were met with statistical significance, irrespective of C-reactive protein (CRP, a marker of inflammation) status or prior exposure to anti-TNF therapy
- CIMZIA was well-tolerated

Olav Hellebo, President of Inflammation Operations at UCB explains, “The robust results from PRECiSE are highly encouraging, suggesting that CIMZIA, a subcutaneously-administered anti-TNF, could offer hope to the thousands of Crohn’s disease patients seeking an effective, well-tolerated, treatment option.”

The PRECiSE clinical trial programme is composed of four studies (PRECiSE 1, 2, 3 and 4). In addition to PRECiSE 2, the detailed results of which were presented for the first time today, PRECiSE 1 is a 26-week double-blind, placebo-controlled trial, and represents the first long-term fully placebo-controlled clinical trial of a biologic in Crohn's disease. PRECiSE 1 successfully met its co-primary endpoints with statistical significance. As expected from a study with such a challenging trial design, top-line results were of lower magnitude than observed in the PRECiSE 2 trial. The detailed analysis of the PRECiSE 1 data is still ongoing, with results planned for presentation at a forthcoming gastroenterology congress. PRECiSE 3 and 4 are both 24-month, open-label trials for patients who participated in either PRECiSE 1 or 2, assessing the longer-term safety and tolerability of CIMZIA, and are currently ongoing.

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Notes to Editors

About Crohn's disease

Crohn's disease is a chronic and ongoing disorder that causes inflammation of the gastrointestinal (GI) tract, most commonly 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 called inflammatory bowel disease. People with Crohn's disease may suffer all of their lives, experiencing an ongoing cycle of "flare-up" and remission. It is estimated that half a million people suffer from Crohn's disease in Europe alone.[2] Symptoms of the disease include diarrhoea, fever, abdominal pain and weight loss which can seriously diminish a patient's quality of life, with many patients also suffering periods of depression.[3]

About CIMZIA™

CIMZIA™ is a unique type of anti-TNF biologic: a Fab' fragment of a humanized anti-TNF-alpha monoclonal antibody chemically attached to polyethylene glycol (PEG, i.e. PEGylated). This PEGylation increases the plasma half-life of CIMZIA to approximately two weeks allowing for four-weekly dosing. CIMZIA is currently the subject of phase III trials in both Crohn's disease and rheumatoid arthritis.

About UCB

UCB (www.ucb-group.com) is a global biopharmaceutical leader with headquarters in Brussels, Belgium, specialising in the fields of central nervous system disorders, allergy and respiratory diseases, immune and inflammatory disorders, as well as oncology. UCB key products are Keppra® (antiepileptic), Xyzal® and Zyrtec® (antiallergics), Nootropil® (cerebral function regulator), Tussionex™ (antitussive) and Metadate™ / Equasym XL™ (attention deficit/hyperactivity disorder). UCB employs over 8,500 people operating in over 40 countries. UCB is listed on Euronext Brussels (UCB / UCBBt.BR / UCB BB).

References

[1] S Schreiber 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) (Abstract to be presented at the 13th United European Gastroenterology Week, 15-19 October 2005)

[2] European Federation of Crohn's & Ulcerative Colitis Associations – EFCA Membership and Population Data (www.efcca.org accessed on 1 April 2004)

[3] Voices of Crohn's Survey (www.crohnsresource.com/voices/key_findings.html accessed on 22 September 2005)