Early Data on Cimzia® from the WELCOME Study Show Efficacy in Infliximab-Refractory Crohn's Disease Patients

First Presentation of Six-Week Data from the WELCOME Study at ECCO

Brussels, Belgium – 4 March 2008 – 7:00 am CET — Six-week data from the WELCOME trial presented at the 3rd congress of the European Crohn's and Colitis Organisation (ECCO) show Cimzia® (certolizumab pegol), the first and only PEGylated anti-TNFα, to be effective in Crohn's patients who are intolerant, or are no longer responding to infliximab.

This is the first presentation of the initial six-week induction results from WELCOME, a 539-patient, Phase IIIb multicentre study of the effects of Cimzia® on Crohn's patients for whom infliximab treatment was not successful. During this six-week induction stage, all patients received 400mg of Cimzia® sub-cutaneous at Weeks 0, 2 and 4. At Week 6, 61 percent of the patients had achieved the primary endpoint of response, defined as a decrease in Crohn's Disease Activity Index (CDAI)* score ≥100 points from baseline. In addition, 39 percent of the patients were in remission, defined as a CDAI score ≤150 points.[1]

"These induction results are very promising," commented study investigator Professor Severine Vermeire of Katholieke Universiteit Leuven, Belgium. "The WELCOME data show that certolizumab pegol could be a treatment option for patients with Crohn's disease who are refractory to other biological agents, showing consistent results across all patient groups."

In the WELCOME study, Cimzia® has demonstrated a low incidence of injection site pain* (less than 2 percent). The most commonly occurring AEs were headache, nasopharyngitis, nausea, vomiting, pyrexia and arthralgia. The incidence of serious adverse events (SAEs) was 7 percent and the most frequent SAEs involved gastrointestinal disorders (5 percent) and infections and infestations (2 percent).[2]

In September 2007, Cimzia® was approved in Switzerland for the treatment of Crohn's disease and it was launched in January 2008.

**** MedDRA Preferred term***

About Cimzia® (certolizumab pegol)

Cimzia® was approved for the treatment of Crohn's Disease in Switzerland in September 2007. In the European Union, the Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion on the market authorisation application (MAA) for Cimzia® in the treatment of patients with Crohn's disease. UCB utilised the appeal process to request a CHMP re-examination of the submission. A decision is expected during the first half of 2008.

Cimzia® has been studied in clinical settings for more than 10 years, beginning with rheumatoid arthritis trials in 1998, and a rigorous clinical trial program in Crohn's disease. Cimzia® has been studied in more than 2000 Crohn's patients totalling over 2200 patient-years of experience.

Cimzia® is the first and only PEGylated anti-TNFα (Tumor Necrosis Factor α). Cimzia® has a high affinity for human TNF-alpha, selectively neutralising 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 WELCOME

*The WELCOME (26-**W**eek open-label trial **E**valuating the clinical benefit and tolerability of certo**L**izumab pegol indu**C**ti**O**n and **M**aintenance in patients suffering from CD with prior loss of response or intol**E**rance to infliximab) study consisted of an initial open-label induction period of six weeks when patients received 400mg of Cimzia® at Weeks 0, 2 and 4. After the induction period, 61 percent of patients had reached the primary endpoint of response (defined as decrease in CDAI score ≥100 points from baseline). Responders at Week 6 were then randomised to either Cimzia® 400mg maintenance every two or every four weeks.[1]*

Participants receiving a concomitant medication were: immunosuppressant (46 percent); corticosteroids (38 percent) or immunosuppressant and corticosteroids (18 percent). Cimzia® was consistently effective across all patient groups. The most common AEs were headache, nasopharyngitis, nausea, vomiting, pyrexia and arthralgia. The incidence of serious adverse events (SAEs) was 7 percent and the most frequent SAEs involved gastrointestinal disorders (5 percent) and infections and infestations (2 percent).[2]

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 usually affects young people between the ages of 15 and 35, with approximately half a million people affected in Europe alone.[3] 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).[3,4]

******* *The CDAI, or Crohn's Disease Activity Index, score measures the severity of CD 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.[5]*

References

1. *Vermeire S et al. Assessment of Certolizumab Pegol in the Treatment of Crohn's Disease in Patients for Whom Infliximab Treatment was not Successful: Open-label Induction Results from the WELCOME Study. Oral presentation at the Congress of European Crohn's and Colitis Organisation, Lyon, France, February 2008.*
2. *Data on file*
3. *Crohn's and Colitis Foundation of America. Disease Information page (www.ccfa.org/info/about/crohns accessed on 3 May 2007).*
4. *European Federation of Crohn's & Ulcerative Colitis Associations Newsletter number 24 May 2006, page 19.*
5. *Best WR et al. Development of a Crohn's disease activity index. National Cooperative Crohn's Disease Study. Gastroenterology; 1976, 70 (3): 439-444.*

About UCB

UCB, Brussels, Belgium (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 the Euronext Brussels Exchange and, through its affiliate, owns approx. 89% of the shares of SCHWARZ PHARMA AG. SCHWARZ PHARMA AG (Monheim, Germany) is a member of the UCB Group.

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