

# Press Release

# CIMZIA<sup>™</sup> Shows Promise in Treatment of Psoriasis

Significant positive results in 12-week phase II trial

**BRUSSELS (Belgium), July 18, 2006 – 7:00 am CET —** UCB today announced significant positive results from the first study to evaluate the efficacy and safety of  $CIMZIA^{TM}$  (certolizumab pegol, CDP870), a new type of anti-tumour necrosis factor (anti-TNF) therapy, in the treatment of patients with moderate to severe psoriasis.

The phase II, randomized, double-blind, placebo-controlled dose-ranging study involved 176 patients with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy and/or photo- or photochemo-therapy. The patients were randomized to one of two different subcutaneous dosing regimens using the liquid formulation: CIMZIA<sup>™</sup> 400mg given every other week, or an initial dose of CIMZIA<sup>™</sup> 400mg followed by a dose of CIMZIA<sup>™</sup> 200mg given every other week; or placebo.

The co-primary endpoints for the study were achieved with a high degree of statistical significance, including the proportion of patients achieving a 75% decrease from baseline in Psoriasis Area and Severity Index score following treatment ('PASI 75') at week 12:

	Placebo	CIMZIA <sup>™</sup> 200mg	CIMZIA <sup>™</sup> 400mg
Percentage of patients achieving PASI 75 at week 12	6.8	74.6 (p<0.001)	82.8 (p<0.001)

Results also suggest CIMZIA<sup>™</sup> to be well-tolerated, with the level of adverse events as expected for an anti-TNF.

"These initial results in psoriasis suggest that certolizumab pegol has the potential to become a highly effective and well-tolerated addition to the biologic treatment options currently available for this difficult-to-treat disease," commented Professor Jean-Paul Ortonne, Hôpital L'Archet, Nice, France and a lead investigator on the trial. "We look forward to the results from further clinical trials confirming these initial findings."

"The data from this first trial in psoriasis are highly encouraging, revealing the tremendous potential for CIMZIA<sup>™</sup> in the treatment of moderate to severe psoriasis, building on the robust efficacy demonstrated in the clinical trials in Crohn's disease, and further reinforcing our commitment to the phase III programme in psoriasis," added Olav Hellebo, President of Inflammation Operations for UCB.

A 24-week follow-up period to this study is currently ongoing, with a retreatment study also in progress. Data from the CIMZIA<sup>™</sup> psoriasis clinical trial programme will be presented at forthcoming dermatology congresses.

UCB submitted requests for regulatory approval for CIMZIA<sup>™</sup> to the U.S. (in February 2006) and European (in April 2006) regulatory authorities for the treatment of Crohn's disease. In addition to the current development programme in Crohn's disease, ongoing phase III studies are investigating the efficacy and tolerability of CIMZIA<sup>™</sup> in the treatment of rheumatoid arthritis.

# About CIMZIA<sup>™</sup>

CIMZIA<sup>™</sup> is the first and only PEGylated Fab' fragment of a humanized anti-TNF-alpha antibody (TNF; Tumour Necrosis Factor). The engineered Fab' fragment retains the biologic potency of the original antibody. CIMZIA<sup>™</sup> 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 Psoriasis

Psoriasis is a chronic skin disease of scaling and inflammation that affects around 125 million people worldwide, including 2% of the European population (one in 50 people). Although the disease occurs in all age groups, it primarily affects adults. Psoriasis occurs when skin cells quickly rise from their origin below the surface of the skin and pile up on the surface before they have a chance to mature. Usually this movement (also called turnover) takes about a month, but in psoriasis it may occur in only a few days.

In its typical form, psoriasis results in patches of thick, red (inflamed) skin covered with silvery scales. These patches, which are sometimes referred to as plaques, usually itch or feel sore. They most often occur on the elbows, knees, other parts of the legs, scalp, lower back, face, palms, and soles of the feet, but they can occur on skin anywhere on the body. The cause of psoriasis is unknown, but it is thought to result from a deficiency in the body's immune system. There is no 'cure' for the disease, which is characterised by outbreaks interspersed by varying periods of remission. Psoriasis can have a markedly negative effect on quality of life, affecting a sufferer's physical, social, and psychological functioning.<sup>1</sup>

#### **Psoriasis Assessment Tools in Clinical Trials**

The 'Gold Standard' for the assessment of extensive psoriasis is the Psoriasis Area and Severity Index (PASI). This measures the average redness, thickness and scaliness of the lesions (each graded on a 0-4 scale), weighted by the area of involvement. PASI 75, a 75% improvement in PASI, is well established as a clinically meaningful endpoint for clinical trials.<sup>2</sup>

#### About UCB

UCB (www.ucb-group.com) is a leading global biopharmaceutical company 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 over 8,300 people in 40 countries, UCB achieved revenues of  $\in 2.3$  billion in 2005. UCB is listed on the Euronext Brussels Exchange. Worldwide headquarters are located in Brussels, Belgium.

# Forward-Looking Statement

This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the safety, efficacy and potential benefits of certolizumab pegol, the development and commercialization of certolizumab pegol. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: the results of research, development and clinical trials; the timing and success of submission, acceptance, and approval of regulatory filings; the time and resources UCB devotes to the development and commercialization of certolizumab pegol and the scope of UCB's patents and the patents of others. In addition, the statements in this press release represent UCB's expectations and beliefs as of the date of this press release. UCB anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while UCB may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing UCB's expectations or beliefs as of any date subsequent to the date of this press.

# References

<sup>1</sup> National Psoriasis Foundation. <u>www.omni.ac.uk/browse/mesh/DO11565.html</u>. Accessed 4 July 2006.

<sup>2</sup> Feldman SR, Krueger GG. Psoriasis assessment tools in clinical trials. *Annals of the Rheumatic Diseases* 2005; **64**: ii65-ii68.

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