



UCB to Appeal European Negative Opinion on CIMZIA[®] for the Treatment of Patients with Crohn's Disease

Brussels (BELGIUM), November 16, 2007 at 7:00 am CET – UCB announced today that it has been informed by the European Medicines Agency (EMA) that the Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion on the market authorisation application (MAA) in the EU for CIMZIA[®] (certolizumab pegol) in the treatment of patients with Crohn's disease.

UCB plans to utilise the appeal process to request a CHMP re-examination of the submission. A decision is expected during the first half of 2008.

"UCB is disappointed by the CHMP decision, but remains confident in the efficacy and tolerability of CIMZIA[®]. UCB will continue to work with the CHMP to address the Committee's concerns to obtain its endorsement to allow this treatment option to be available to people suffering from Crohn's disease." said Melanie Lee, Executive Vice President Research & Development of UCB.

About CIMZIA[®]

CIMZIA[®] is the only PEGylated anti-TNF (Tumour Necrosis Factor). 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 filed a Biologics License Application (BLA) with the Food and Drug Administration (FDA) for CIMZIA[®] in the treatment of Crohn's disease on February 28, 2006. CIMZIA[®] was approved in Switzerland for the treatment of Crohn's disease in September 2007. Preparation for a regulatory submission for CIMZIA[®] in the treatment of rheumatoid arthritis in the U.S. is ongoing.

The MAA was based on the pivotal PRECiSE studies involving over 1,500 patients with Crohn's disease.^{1,2}

Further information

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References

1. Sandborn WJ et al. Certolizumab pegol for the treatment of Crohn's disease. *NEJM* 2007; 357: 228-38.
2. Schreiber S et al. Maintenance therapy with certolizumab pegol for Crohn's disease. *NEJM* 2007; 357: 239-50.



About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a global leader in the biopharmaceutical industry 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 more than 10,000 people in over 40 countries, UCB achieved revenue of 3.5 billion euro in 2006 on a pro forma basis. 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).

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.