



## FDA AGREES TO REVIEW CIMZIA® FILE FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

**Brussels, Belgium - February 6, 2008 at 7:00 am CET** - UCB today announced that the U.S. Food and Drug Administration (FDA) agreed to accept, for filing and review, a biologics license application (BLA) for Cimzia® (certolizumab pegol) for the treatment of adult patients with active rheumatoid arthritis (RA). Cimzia® is an investigational agent. If approved, Cimzia® will be the first and only PEGylated anti-TNF (Tumor Necrosis Factor) biologic therapy available for the treatment of rheumatoid arthritis.

"As a new anti-TNF, we believe that Cimzia® would provide an important new option for people living with this disease," said Olav Hellebo, President Inflammation Operations, UCB.

The BLA is based on data from more than 2,367 patients and includes three multi-center, placebo-controlled Phase III trials which were recently presented at the American College of Rheumatology (ACR) Annual Scientific Meeting.

In these studies Cimzia®, given with methotrexate, was shown to be significantly more effective than methotrexate alone for the inhibition of joint damage progression in patients with active RA as early as 24 weeks (RAPID 1 and RAPID 2). Cimzia® was shown to rapidly reduce the signs and symptoms of active RA with peak ACR50 and 70 responses achieved at 14 and 16 weeks. Improvement in physical function and quality of life measures were also seen for up to one year (RAPID 1). Further, Cimzia® administered as monotherapy showed significant improvement in signs and symptoms of RA from week 1 and this benefit was maintained through week 24 (Study 011). The most commonly occurring adverse reactions, were headache, nasopharyngitis, and upper respiratory tract infections. Reported serious adverse reactions were infections (including tuberculosis) and malignancies (including lymphoma), consistent with findings from other trials in the anti-TNF class.

Preparation for submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Cimzia® in the treatment of RA is ongoing, with filing planned in the first half of 2008.

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



### **About Rheumatoid Arthritis**

RA is a progressive autoimmune disease that causes chronic inflammation of the joints. It is estimated that five million people suffer from RA globally, with 0.3 percent to 1 percent of the population in industrialized countries suffering from the disease. Women are three times more likely to be affected than men. Although it can affect people of all ages, the onset of RA usually occurs between the ages of 35-55.

Traditional treatments for RA include nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids and disease-modifying antirheumatic drugs (DMARDs), with biological therapies a more recent addition.

### **Further information**

#### **UCB**

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### **About UCB**

*UCB, Brussels, Belgium ([www.ucb-group.com](http://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 around 12,000 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 Euronext Brussels.*

### **UCB Forward-Looking Statement**

*This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the development and commercialization of levocetirizine. 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 levocetirizine and the scope of UCB's patents and the patents of others.*