UCB's meeting with U.S. FDA defines path forward for Cimzia® in rheumatoid arthritis.

- **No new studies required**
- **UCB to submit the response for Cimzia® (*certolizumab pegol*) in the second quarter of this year**

Brussels (Belgium), 6th February, 2009 – 07:00 AM (CET) - press release, regulated information - UCB announced today that it met the U.S. Food and Drug Administration (FDA) and clarified the requirements for the approval of the Biologics License Application (BLA) for Cimzia®, the first PEGylated anti-TNF, for the treatment of rheumatoid arthritis (RA).

During the meeting, the FDA communicated that they require further analysis of existing data and a new safety update. No additional studies (clinical or non-clinical) are needed to fulfill this request.

"UCB is working diligently with the FDA to fulfil its request and, due to the already rich database available for Cimzia® in rheumatoid arthritis, we anticipate submitting the full response for Cimzia® in the second quarter of this year," said Prof. Dr. Iris Loew-Friedrich, Chief Medical Officer of UCB.

In January this year, UCB received a Complete Response Letter from the FDA in connection with the Cimzia® BLA. The BLA, accepted for filing and review in February 2008, was based on a clinical program conducted by UCB which included more than 2,300 patients, representing more than 4,000 patient years of experience and involved several multi-centre placebo-controlled Phase III trials.

On April 22, 2008, the FDA approved Cimzia® for reducing the signs and symptoms of Crohn's disease, and maintaining clinical response, in adult patients with moderate to severe active disease that have had an inadequate response to conventional therapy. Cimzia® is also approved in Switzerland for the induction of a clinical response, and for the maintenance of a clinical response and remission, in patients with active Crohn's disease who have not responded adequately to conventional treatment.

Cimzia® is also undergoing active review by the European authorities for the treatment of RA.

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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 % to 1 % 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 non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and disease-modifying antirheumatic drugs (DMARDs), with biological therapies a more recent addition.

About CIMZIA®

Cimzia® is the only PEGylated anti-TNF (Tumor 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. The U.S. Food and Drug Administration (FDA) has approved Cimzia® for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have had an inadequate response to conventional therapy. Cimzia® was approved in Switzerland for induction of a clinical response and for the maintenance of a clinical response and remission in patients with active Crohn's disease who have not responded adequately to conventional treatment in September 2007. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus in the fields of central nervous system and immunology disorders. Employing more than 10 000 people in over 40 countries, UCB aims to achieve revenues of at least EUR 3.3 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

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.