UCB receives Complete Response Letter from U.S. FDA for use of Cimzia® in rheumatoid arthritis patients

Brussels (Belgium), 5 January, 2009 at 6:00 pm CET - Press release – regulated information — UCB announced today that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) relating to the Biologics License Application (BLA) of Cimzia® (*certolizumab pegol*), the first PEGylated anti-TNF, for the treatment of rheumatoid arthritis (RA).

As a prerequisite for approval of Cimzia® in RA, the FDA has requested a new safety update with all clinical data including new data generated since the filing of the BLA. The FDA has invited UCB for a meeting, expected to take place within approximately 30 days, to define the path forward.

"UCB is confident and committed to making Cimzia® available to people living with moderate to severe rheumatoid arthritis and other inflammatory conditions as soon as possible. UCB will work diligently with the FDA to fulfill its request," said Prof. Dr. Iris Loew-Friedrich, Chief Medical Officer of UCB.

The BLA, accepted for filing and review in February 2008, was based on a clinical programme conducted by UCB which included more than 2 300 patients (representing more than 4 000 patient years of experience) involved in several multi-centre placebo-controlled Phase III trials.

On April 22, 2008, the FDA approved Cimzia® for reducing 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.

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 nonsteroidal 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 S.A.

For further information

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About UCB

UCB Brussels, Belgium (www.ucb-group.com) is a global biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 10 000 people in over 40 countries, UCB expects to achieve revenue of 3.3 billion euro in 2008. UCB is listed on Euronext Brussels (symbol: UCB). The company's U.S. headquarters is located in Atlanta.

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