UCB's Cimzia® filed with EMEA for treatment of rheumatoid arthritis

The European marketing authorisation application for Cimzia® has been filed. Subject to approval, Cimzia® will be the first and only PEGylated, Fc-Free anti-TNF (Tumour Necrosis Factor alpha) biologic therapy.

BRUSSELS, BELGIUM – July 1st 2008 – 7:00 am CET — UCB today announced that a Marketing Authorisation Application (MAA) has been submitted to the European Medicines Agency (EMEA) requesting the approval of Cimzia® (certolizumab pegol) as a subcutaneous treatment for adults with moderate to severe active rheumatoid arthritis (RA) and has been accepted for review. Subject to approval, Cimzia® will be the first and only PEGylated, Fc-Free anti-TNF (Tumour Necrosis Factor alpha) biologic therapy available in Europe for the treatment of RA.

"Along with a fast onset of action, Cimzia® has been shown to rapidly reduce the rate of progression of joint damage and to improve measurements of patients' physical function," said Olav Hellebo, President of Inflammation Operations for UCB. "With millions of people suffering from rheumatoid arthritis across the globe, Cimzia®, when approved, will provide a new and effective treatment option for this debilitating condition."

The MAA filing is based on UCB's clinical programme with data from more than 2,300 patients involved in several multi-centre placebo-controlled Phase III trials totaling over 4,000 patient-years of experience. Cimzia® has been studied at two or four week dosing intervals, and administered together with methotrexate (MTX) or as monotherapy.

In the RAPID trials, Cimzia® together with MTX demonstrated a rapid and significant reduction in the signs and symptoms of active RA as early as Week 1 and inhibited progression of structural damage, with results maintained through to week 52 ($p<0.001$). Patients in the RAPID 1 trial also experienced fast and clinically significant improvement in physical function, pain and fatigue from Week 1 and for up to one year ($p<0.001$).

A pooled analysis of the safety data from the two RAPID studies showed there was a low incidence of injection site pain (n=<3 new cases/ 100 patient-years) and low level of discontinuations due to adverse events (AEs). The most commonly occurring AEs 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.

This European filing follows the February 2008 Biologics License Application (BLA) with the United States Food and Drug Administration (FDA) for Cimzia® for the treatment of adult patients with active rheumatoid arthritis (RA). On April 22, 2008, the US Food and Drug Administration (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 who have had inadequate response to conventional therapy. Cimzia® has been available to doctors and patients in the US since April 24, 2008.

Further information

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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 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.

About Cimzia® (certolizumab pegol)

Cimzia® is the first and 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. UCB is developing Cimzia® in Crohn's disease, rheumatoid arthritis and other autoimmune disease indications. The US Food and Drug Administration (FDA) has approved Cimzia® (certolizumab pegol), for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have an inadequate response to conventional therapy. Cimzia® is a registered trademark of UCB PHARMA S.A.

About UCB

UCB (Brussels, Belgium) (www.ucb-group.com) is a global leader in the biopharmaceutical industry 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 around 12 000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2007. UCB S.A. is listed on Euronext Brussels.

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.