



New Cimzia® study shows rapid reduction of symptoms and progression of rheumatoid arthritis

Patients treated with Cimzia®, together with methotrexate (MTX), experienced a rapid and clinically significant improvement in physical function, pain and fatigue as early as week one.

Brussels, Belgium, October 30, 2008 — UCB announced pivotal RAPID 1 (RA Prevention of structural Damage) data published in *Arthritis & Rheumatism* shows CIMZIA® (*certolizumab pegol*), the only PEGylated anti-TNF (Tumour Necrosis Factor alpha), together with methotrexate (MTX), rapidly reduced symptoms of disease and inhibited progression of joint damage in adult patients with active rheumatoid arthritis (RA), with sustained results for up to one year.

"In the RAPID 1 study Cimzia®, together with MTX, had a rapid onset of action and inhibited structural damage early in adults with rheumatoid arthritis. This demonstrated a clear therapeutic benefit for patients with a reduction in swollen and tender joints, pain and fatigue as early as one week after treatment, and signs of preventing long-term structural damage by 16 weeks," said lead investigator Edward Keystone, M.D., The Rebecca MacDonald Center for Arthritis, Mount Sinai Hospital, The University of Toronto.

The one year study showed Cimzia®, together with MTX, had a rapid and significant effect in reducing the signs and symptoms of active RA as early as week one and shown by a significant difference in ACR20 and 50 responses with Cimzia® compared with placebo, by Week 1 and Week 2 respectively ($p < 0.001$ and $p < 0.01$). Peak responses achieved at 12 and 14 weeks were sustained throughout the study.

Patients treated with Cimzia®, together with MTX, experienced significant improvements in physical function and quality of life from Week 1 and sustained for up to one year, measured by mean change from baseline in HAQ-DI ($p < 0.001$).

Radiographic data showed Cimzia®, together with MTX, inhibited progression of RA, with a significantly smaller change from baseline in modified Total Sharp Score (TSS) at 24 and 52 weeks of treatment, compared with MTX alone ($p < 0.001$). A significant difference between patients on Cimzia®, together with MTX, and placebo was observed as early as 16 weeks in clinical non-responders ($p < 0.001$).

"Cimzia® is the first anti-TNF to demonstrate such early results in disease progression. UCB looks forward to bringing these benefits to people who suffer from RA once the regulatory review process is completed," said Iris Loew-Friedrich, MD, PhD, Chief Medical Officer, UCB.

RAPID 1 and a simultaneous study, RAPID 2, are the first large, placebo-controlled Phase III trials demonstrating the efficacy and tolerability of Cimzia® in the treatment of RA, as part of clinical trials programme involving more than 2,300 patients.



Pooled safety data from both studies showed Cimzia[®] was generally well tolerated with a low incidence of injection site pain (n=<3 new cases /100 years) and 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.

"With more than five million people suffering from RA across the globe, RAPID 1 showed that, upon successful regulatory review, Cimzia[®] can provide a treatment option for patients seeking a rapid and effective therapy to manage this debilitating condition," said principle investigator Professor Bernard Combe, Montpellier University Hospital, France.

The U.S. Food and Drug Administration (FDA) accepted a Biologics License Application for Cimzia[®] for the treatment of adult patients with active RA in February 2008. UCB submitted a Marketing Authorisation Application to the European Medicines Agency in June 2008 requesting the approval of Cimzia[®] as a subcutaneous treatment for adults with moderate to severe active RA.

About RAPID 1

The double-blind placebo-controlled trial, involving 982 adults, was designed to establish the efficacy and tolerability of Cimzia[®] together with MTX, in the treatment of active RA in patients who did not adequately respond to conventional treatment. Patients were randomly allocated to receive one of three treatment regimens: 393 patients received Cimzia[®] 400 mg and at Weeks 0, 2 and 4, then 200 mg every two weeks; 390 patients received Cimzia[®] 400 mg every 2 weeks; 199 patients received placebo every 2 weeks. RAPID 1 met co-primary endpoints: ACR20 response rate at Week 24 and change from baseline in mTSS at Week 52.

About Cimzia[®] (certolizumab pegol)

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. The US 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 the treatment of Crohn's Disease in September 2007. UCB is also developing Cimzia[®] in rheumatoid arthritis and other autoimmune disease indications. Cimzia[®] is a registered trademark of UCB S.A.

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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 medicines with focus on the fields of central nervous system and immunology disorders. Employing around 12,000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2007. 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.