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Press Release

CIMZIA™ Effective in Reducing Signs and Symptoms of Rheumatoid Arthritis

New data presented at EULAR confirms efficacy with either every two weeks or monthly dosing

Barcelona, Spain, 14 June 2007 – 7:00 am CET — New pivotal data (RAPID 1 and RAPID 2) presented at the Annual European Congress of Rheumatology (EULAR) show that CIMZIA™ (certolizumab pegol), the first PEGylated, Fc-free anti-TNF, combined with methotrexate therapy has a rapid and significant effect in reducing the signs and symptoms of active rheumatoid arthritis (RA) compared with methotrexate alone. Data from a third study, the 011 trial, presented at the conference also showed that CIMZIA™ given every four weeks as monotherapy is significantly more efficacious than placebo in the treatment of patients with active RA who had previously failed disease-modifying anti-rheumatic drug (DMARD) therapy.

In both pivotal Phase III studies, RAPID 1 and RAPID 2, the primary endpoint, ACR20[a] response at 24 weeks, was significantly higher in both CIMZIA™ treated arms (400 mg at week zero, week two and week four followed by 200 mg every two weeks plus methotrexate; or 400 mg every two weeks plus methotrexate) compared with the placebo plus methotrexate-treated arm ($p<0.001$). In both studies there was no significant difference between response levels in either of the CIMZIA™ treatment arms. ACR50 and ACR70 responses were also achieved rapidly and with statistical significance in both studies in the CIMZIA™ treated arms.

RAPID 1 and RAPID 2 demonstrated that effective results in the treatment of RA can be achieved with a 200 mg every other week dose of CIMZIA™ — the higher dose is not necessary. CIMZIA™ was also shown to have a rapid onset of action: in RAPID 1, a 25.4% ACR50 response rate was observed at week 8 in both treatment groups.

“These results are significant. They showed, for the first time, that the Fc region present in conventional anti-TNFs is not required for activity in rheumatoid arthritis – and it is this region that has often been associated with cellular cytotoxicity,” commented Professor Edward Keystone, Professor of Medicine, University of Toronto, Canada. “The consistency of the RAPID data confirm that certolizumab pegol may provide a valuable new treatment option for patients with this condition.”

The safety and tolerability profile of CIMZIA™ in both RAPID studies was consistent with that expected of an anti-TNF agent.

In another study presented at the meeting, the 011 trial, the efficacy of CIMZIA™ 400 mg every four weeks as monotherapy was compared with that of placebo in treating the signs and symptoms of RA in patients who had previously failed on one or more courses of a DMARD. The primary endpoint, ACR20 response at 24 weeks, was significantly higher in the CIMZIA™ treated arm than in the placebo treated arm (45.5% vs 9.3%: $p<0.001$). ACR50 and ACR70 responses were also both achieved with statistical significance. CIMZIA™ was also significantly superior to placebo in terms of median time to first ACR20 response (2.0 vs 19.9 weeks, $p<0.001$), with 80.6% of ACR20 responders having achieved response by week 1.

“These data show the potential of certolizumab pegol to safely and effectively treat patients who have previously failed disease modifying antirheumatic drug treatments,” added Prof. Josef Smolen, Chairman of the Department of Rheumatology, Medical University of Vienna, Austria. "In addition, certolizumab pegol could provide a valuable option in patients who are unable to take or cannot tolerate methotrexate.”

Preparation for a regulatory submission for CIMZIA™ in the treatment of RA is ongoing, with filing planned by the end of 2007.

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[a] ACR (American College of Rheumatology) response scores measure improvement in the tender and swollen joint count and also include assessment of the following five parameters: patient's global assessment, physician's global assessment, patient's assessment of pain, degree of disability, and level of acute-phase reactant. ACR20 is achieved when there is 20% improvement in the tender and swollen joint count as well as a 20% improvement in at least three of the five parameters. ACR50 & ACR70 are an extension of these criteria corresponding to a 50% and 70% improvement respectively.[1]

Notes to Editors:

RAPID Clinical Trials Program

The RAPID series of clinical trials were designed to establish the efficacy and tolerability of CIMZIA™ (certolizumab pegol) in the treatment of rheumatoid arthritis. The RAPID clinical trial programme is composed of two large, international, multi-centre placebo-controlled studies – RAPID 1 (027) and RAPID 2 (050).

In the 52-week RAPID 1 trial, 992 patients were randomly allocated to receive one of three treatment regimens:

- 397 patients received 400 mg lyophilized CIMZIA™ at the start of the study and at weeks two and four, then 200 mg given every two weeks, together with methotrexate;
- 394 patients received 400 mg lyophilized CIMZIA™ every two weeks, together with methotrexate;
- 201 patients received placebo every two weeks, together with methotrexate.

In all three arms of the study, the dose of methotrexate was 10 mg per week or greater.

Co-primary endpoints for the study RAPID 1 were the ACR20 responder rate at week 24 and the change from baseline in mTSS at week 52. These data on radiographic progression will be presented at a forthcoming rheumatology congress.

24-Week ACR Responses for RAPID 1

	Placebo & MTX	***CIMZIA™ (certolizumab pegol) 200mg & MTX***	***CIMZIA™ (certolizumab pegol) 400mg & MTX***
ACR 20	14	59*	61*
ACR 50	8	37*	40*
ACR 70	3	21*	21*

* p<0.001

In the 24-week RAPID 2 trial, 634 patients were randomly allocated to receive one of three treatment regimens:

- 252 patients received 400 mg liquid CIMZIA™ at the start of the study and at weeks two and four, then 200 mg given every two weeks, together with methotrexate;
- 252 patients received 400 mg liquid CIMZIA™ every two weeks, together with methotrexate;
- 130 patients received placebo every two weeks, together with methotrexate.

In all three arms of the study the dose of methotrexate was 10mg per week or greater.
Patients were assessed for improvement in signs and symptoms of RA. The primary endpoint for the study RAPID 2 was ACR20 responder rate at week 24.

24-Week ACR Responses for RAPID 2

	Placebo & MTX	***CIMZIA™ (certolizumab pegol) 200mg & MTX***	***CIMZIA™ (certolizumab pegol) 400mg & MTX***
ACR 20	9	57*	58*
ACR 50	3	32*	33*
ACR 70	1	16*	11*

* p<0.001

011 Trial

In the 24-week 011 phase III study, 220 adult patients with active RA who had previously failed at least one DMARD were randomized to receive either CIMZIA™ 400 mg given subcutaneously every four weeks (n=111) or placebo (n=109). Patients were assessed for improvement in signs and symptoms of RA. The primary endpoint of the 011 study was ACR20 responder rate, with secondary measures including ACR50 and ACR70 responder rates.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a progressive autoimmune disease which causes chronic inflammation of the joints. It is estimated that 5 million people suffer from RA globally,[2] with 0.3% to 1% of the population in industrialized countries suffering from RA.[3]

Prevalence is not split evenly between genders, since women are three times more likely to be affected than men.[4] Although it can affect people of all ages, the onset of RA usually occurs between the ages of 35-55 years.[5]

Symptoms of RA include joint stiffness, joint pain, inflammation of the affected areas and an associated reduction in mobility. These symptoms can be intermittent and vary in severity from patient to patient. In more severe cases RA can eventually lead to disability. RA patients are also at a higher risk of developing other conditions, in particular heart disease, stroke, infections, lung problems and osteoporosis.[6]

As there is currently no cure for RA, treatment goals centre on disease management. Treatment is aimed at controlling disease progression, providing pain relief and reducing swelling, preventing joint damage and deformity and maintaining function of the affected joints to prevent disability.

Traditional treatments for RA include nonsteroidal anti-Inflammatory drugs (NSAIDs), corticosteroids and disease modifying antirheumatic drugs (DMARDs), with biological therapies a more recent addition to the list of treatment options. Anti-TNF (TNF-alpha; Tumour Necrosis Factor) therapies are specific types of monoclonal antibody (biological therapies) which have been approved for use in patients with RA. They may be given alone but are usually given in combination with methotrexate or another immunosuppressant. Anti-TNF therapies have proven to be effective treatments, with the potential to prevent joint damage. They work by inhibiting the action of TNF-alpha, an inflammatory mediator, either directly or indirectly responsible for damaging the joint.[6]

About CIMZIA™ (certolizumab pegol)

CIMZIA™ (certolizumab pegol) is an investigational drug product. CIMZIA™ is the first and only PEGylated Fc-free anti-TNF (Tumour Necrosis Factor), and is being evaluated in RA at a dosing of once every two weeks and once every four weeks, via subcutaneous administration. CIMZIA™ has demonstrated efficacy without the possible cytotoxicity mediated by the Fc portion present in conventional anti-TNFs.

CIMZIA™ has a high affinity for human TNF-alpha, selectively targeting TNF-alpha in inflamed tissue. 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 filed a Biologics License Application (BLA) with the Food and Drug Administration (FDA) for CIMZIA™ in the treatment of Crohn's disease on February 28, 2006 and on April 28, 2006

submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for the same indication.

About UCB

Headquartered in Brussels (Belgium), UCB (www.ucb-group.com) is a leading global biopharmaceutical company 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 more than 8,400 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange and owns 87.6% of Schwarz Pharma.

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