



UCB's Cimzia[®] (certolizumab pegol) approved by the U.S. FDA for adult patients suffering from moderate to severe rheumatoid arthritis

- Available this week, Cimzia[®] (*certolizumab pegol*), the only pegylated anti-TNF, offers a new treatment option for U.S. adult patients suffering from moderately to severely active rheumatoid arthritis
- Patients treated with Cimzia[®], together with methotrexate, experienced rapid and significant improvements in signs and symptoms, physical function and pain as early as week one, and sustained at week 24 and for up to one year
- Patients treated with Cimzia[®] as a monotherapy experienced significant improvements in signs and symptoms, physical function and pain
- Cimzia[®] is available in an exclusively designed, patient-friendly, prefilled syringe resulting from the UCB partnership with OXO[®]. The new syringe carries the Arthritis Foundation[™] Ease-of-Use Commendation
- Cimzia[®] offers U.S. adult patients flexible maintenance dosing, either at two or four weeks after initial doses, and can be used together with methotrexate or as a monotherapy

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UCB announced today that the U.S. Food and Drug Administration (FDA) approved Cimzia[®], the only PEGylated anti-TNF (Tumor Necrosis Factor), for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). Cimzia[®] can be dosed at 400 mg initially and at weeks two and four, followed by 200 mg every other week; for maintenance dosing, 400 mg every four weeks can be considered.

In clinical trials with Cimzia[®], together with methotrexate (MTX), patients experienced a significant reduction in the signs and symptoms of RA at week 24 with some showing clinical responses within one to two weeks, compared with MTX alone. Additionally, radiographic data showed Cimzia[®], together with MTX, inhibited progression of joint damage, 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).

"The approval of Cimzia[®] for moderate to severe rheumatoid arthritis in the U.S. is a major milestone for UCB, and most importantly, for people seeking a new treatment option to manage this debilitating condition," said Roch Doliveux, Chief Executive Officer of UCB. "UCB is committed to developing new therapies, such as Cimzia[®], to help meet the needs



of patients living with rheumatoid arthritis and other immune diseases. I am also proud of our partnership with OXO[®] and of the fact that RA patients were directly involved in the design and development of our new prefilled syringe, which is designed to make self-administration easy for people living with rheumatoid arthritis.”

The new prefilled Cimzia[®] syringe is now also available for subcutaneous self-administration to U.S. patients with moderate to severe Crohn’s disease who have had an inadequate response to conventional therapy.

The FDA approval is based on UCB’s comprehensive clinical program, including data from four multi-center placebo-controlled phase III trials, involving more than 2 300 patients with RA and over 4 000 patient-years experience. Cimzia[®] has been studied at dosing intervals of two or four weeks, and administered together with MTX or as monotherapy.

In the pivotal clinical trials, reported serious adverse reactions were infections including tuberculosis and malignancies including lymphoma. The most commonly occurring adverse events were upper respiratory tract infections, rash and urinary tract infections. A pooled analysis of the safety data show there was a low incidence of injection site pain (<2%) and a low level of discontinuations due to adverse events (5%).

“People with RA have pain and swelling of joints with stiffness and fatigue which makes it difficult for them to perform many activities of daily living, sometimes making it a struggle to even get out of bed,” said Roy Fleischmann, MD, Clinical Professor in the Department of Internal Medicine at the University of Texas Southwestern Medical Center in Dallas. “With the approval of Cimzia[®], I now have another alternative to offer my patients in an easy-to-use treatment that improves quality of life and inhibits structural damage.”

It is estimated that 5 million people suffer from RA globally. In the United States alone, an estimated 1.3 million people have the disease. Prevalence is not split evenly between genders, since women are three times more likely to be affected than men. Although RA can affect people of all ages, the onset of the disease usually occurs between 35-55 years of age.

For further information

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Notes to the editor:

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 and for the treatment of adults with moderate to severely active rheumatoid arthritis. 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.

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IMPORTANT SAFETY INFORMATION

Patients treated with Cimzia® are at an increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Cimzia® should be discontinued if a patient develops a serious infection or sepsis.

Reported infections include:

- ***Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Cimzia® use and during therapy. Treatment for latent infection should be initiated prior to Cimzia® use.***
- ***Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.***
- ***Bacterial, viral and other infections due to opportunistic pathogens.***

The risks and benefits of treatment with Cimzia® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Cimzia®, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Serious and sometimes fatal infection due to bacterial, mycobacterial, invasive fungal, viral or other opportunistic pathogens has been reported in patients receiving TNF-blocking agents. Among opportunistic infections, tuberculosis, histoplasmosis, aspergillosis, candidiasis, coccidioidomycosis, listeriosis, and pneumocystosis were the most common. Treatment with Cimzia® should not be initiated in patients with an active infection, including clinically important localized infections. The risks and benefits of treatment should be considered prior to initiating therapy in patients with chronic or recurrent infection, who have been exposed to tuberculosis, who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, or with underlying conditions that may predispose them to infection.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating Cimzia® and periodically during therapy. Patients should be closely monitored for the development of signs and symptoms of infections during and after treatment with Cimzia®, including



development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy. Cimzia® should be discontinued if a patient develops a serious infection or sepsis. Patients who develop a new infection during treatment with Cimzia® should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for immunocompromised patients, and appropriate antimicrobial therapy should be initiated. Appropriate empiric antifungal therapy should also be considered while a diagnostic workup is performed for patients who develop a serious systemic illness and reside or travel in regions where mycoses are endemic.

During controlled and open-labelled portions of Cimzia® studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate (95% confidence interval) of 0.5 (0.4, 0.7) per 100 patient-years among 4,650 Cimzia®-treated patients versus a rate of 0.6 (0.2, 1.7) per 100 patient-years among 1,319 placebo-treated patients. The size of the control group and limited duration of the controlled portions of the studies preclude the ability to draw firm conclusions. In studies of Cimzia® for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 Cimzia®-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. In Cimzia® RA clinical trials (placebo-controlled and open label) a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of TNF blocker therapy in the development of malignancies is not known.

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Cimzia® has not been formally studied in patients with CHF. Exercise caution when using Cimzia® in patients who have heart failure and monitor them carefully.

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following Cimzia® administration. If such reactions occur, discontinue further administration of Cimzia® and institute appropriate therapy.

Use of TNF blockers, including Cimzia®, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating Cimzia® therapy. Exercise caution in prescribing Cimzia® for patients identified as carriers of HBV. Patients who are carriers of HBV and require treatment with Cimzia® should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy. In patients who develop HBV reactivation, discontinue Cimzia® and initiate effective anti-viral therapy with appropriate supportive treatment.

Use of TNF blockers, including Cimzia®, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with Cimzia®; the causal relationship to Cimzia® remains unclear. Exercise caution in considering the use of Cimzia® in patients with these disorders.

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently reported with Cimzia®. The causal relationship of these events to Cimzia® remains unclear. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia®. Consider discontinuation of

Cimzia® therapy in patients with confirmed significant hematologic abnormalities.

An increased risk of serious infections has been seen in clinical trials of other TNF blocking agents used in combination with anakinra or abatacept. Formal drug interaction studies have not been performed with rituximab or natalizumab; however because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of Cimzia® in these combinations. Therefore, the combination of Cimzia® with anakinra, abatacept, rituximab, or natalizumab is not recommended.

Treatment with Cimzia® may result in the formation of auto antibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Do not administer live vaccines or attenuated vaccines concurrently with Cimzia®.



Interference with certain coagulation assays has been detected in patients treated with Cimzia®. There is no evidence that Cimzia® therapy has an effect on in vivo coagulation. Cimzia® may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities.

In controlled Crohn's clinical trials, the most common adverse events that occurred in ≥5% of Cimzia® patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% Cimzia®, 13% placebo), urinary tract infection (7% Cimzia®, 6% placebo), and arthralgia (6% Cimzia®, 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for Cimzia® and 7% for placebo.

In controlled RA clinical trials, the most common adverse events that occurred in ≥ 3% of patients taking Cimzia® 200 mg every other week with concomitant methotrexate (n=640) and more frequently than with placebo with concomitant methotrexate (n=324) were upper respiratory tract infection (6% Cimzia®, 2% placebo), headache (5% Cimzia®, 4% placebo), hypertension (5% Cimzia®, 2% placebo), nasopharyngitis (5% Cimzia®, 1% placebo), back pain (4% Cimzia®, 1% placebo), pyrexia (3% Cimzia®, 2% placebo), pharyngitis (3% Cimzia®, 1% placebo), rash (3% Cimzia®, 1% placebo), acute bronchitis (3% Cimzia®, 1% placebo), fatigue (3% Cimzia®, 1% placebo). Hypertensive adverse reactions were observed more frequently in patients receiving Cimzia® than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs. Patients receiving Cimzia® 400mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving Cimzia® 200mg every other week. The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for Cimzia® and 2.5% for placebo. Please see full prescribing information on www.Cimzia.com.

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 on the fields of central nervous system and immunology disorders. Employing approximately 10 000 people in over 40 countries, UCB generated revenue of EUR 3.6 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

Forward-looking statements

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.