



UCB shows strong scientific presence at leading rheumatology meeting

- Data to be presented at the ACR/ARHP Annual Meeting on UCB's marketed product CIMZIA[®] (certolizumab pegol) and the company's immunology investigational pipeline reinforce UCB's dedicated focus on improving the lives of people with severe diseases

Brussels, Belgium and Atlanta, U.S. – November 14th 2014, 0700 CET – UCB, a global biopharmaceutical company is sponsoring 27 data presentations at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting, November 14 – 19, 2014 in Boston, MA. The multiple presentations will include the latest data evaluating the long-term efficacy and safety of certolizumab pegol (marketed as CIMZIA[®]) for the treatment of moderate to severe rheumatoid arthritis and psoriatic arthritis as well as for investigational use in axial spondyloarthritis including ankylosing spondylitis and non-radiographic axial spondyloarthritis. Data will also be presented on epratuzumab, an investigational medicine in Phase 3 clinical development for systemic lupus erythematosus (SLE), and on romosozumab, an investigational medicine in Phase 3 clinical development for osteoporosis.

“UCB is pleased to sponsor multiple immunology presentations at ACR 2014 including oral and poster presentations on CIMZIA[®] as well as investigational data from our pipeline. The depth and breadth of presentations highlight our dedicated focus on delivering new and innovative treatment options and support our efforts to improve disease management for people with severe diseases.” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. “Data presentations from our pipeline on epratuzumab and romosozumab reflect our valued partnerships with pharmaceutical companies and research institutions who share our goals.”

In the US, CIMZIA[®] is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis, for the treatment of adults with active psoriatic arthritis (PsA) and for adults with active ankylosing spondylitis (AS).¹ In addition, it is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.¹ See important safety information including risk of serious infections and tuberculosis below.

In the EU, CIMZIA[®] in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX.² CIMZIA[®] can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. CIMZIA[®], in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. CIMZIA[®] can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.² CIMZIA[®] is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:²

- Ankylosing spondylitis (AS) - adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs [NSAIDs]).
- Axial spondyloarthritis (axSpA) without radiographic evidence of AS - adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI), who have had an inadequate response to, or are intolerant to NSAIDs.²

Epratuzumab is licensed from Immunomedics Inc. and is not approved for the treatment of SLE by any regulatory authority worldwide.

Romosozumab is being co-developed by UCB and Amgen and is not approved for the treatment of osteoporosis by any regulatory authority worldwide.

Following is a guide to the UCB-sponsored data presentations:

Presentations on CIMZIA® in Rheumatoid Arthritis

1. **[1844]: Identification of a Patient Phenotype which Impacts Response to Therapy in Rheumatoid Arthritis Clinical Trials: Certolizumab Pegol Phase 4 Trial Data**
Curtis, J. *et al.*
 - Date/Time: Monday November 17th; 15:00 – 15:15
 - Session Info: Oral Presentation, Exhibit Hall C
2. **[464]: Analysis of Pooled Data from Two Randomized Controlled Trials and Their Open-Label Extensions: Long-Term Safety in Rheumatoid Arthritis Before and After Certolizumab Pegol Dose Increase/Decrease**
Haraoui, B. *et al.*
 - Date/Time: Sunday November 16th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B
3. **[2475]: Multiple Approaches For Implementation of Long-Term Efficacy: Interpretation of Certolizumab Pegol Data in Rheumatoid Arthritis Case Study**
Keystone, E. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B
4. **[2472]: The First, Multicenter, Double-Blind, Randomized, Parallel-Group Study of Certolizumab Pegol in Early Rheumatoid Arthritis Demonstrates Inhibition of Joint Damage Progression**
Atsumi, T. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B
5. **[1180]: Dynamic Magnetic Resonance Imaging in the Assessment of the Response to Certolizumab Pegol in Rheumatoid Arthritis Patients: Results from a Phase IIIb**

Randomized Study**Østergaard, M. *et al.***

- Date/Time: Monday November 17th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

6. [468]: Identification of Baseline Risk Factors for Adverse Events in Certolizumab Pegol Treated Rheumatoid Arthritis Patients**Haraoui, B. *et al.***

- Date/Time: Sunday November 16th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

7. [102]: Real-World Utilization, Patient Characteristics and Persistency of Certolizumab Pegol vs Other Anti-TNFs for the Treatment of Rheumatoid Arthritis in the United Kingdom
Humby, F. *et al.*

- Date/Time: Sunday November 16th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

Presentations on CIMZIA® in Psoriatic Arthritis**8. [545]: Long-Term Safety and Efficacy of Certolizumab Pegol over 96 Weeks in Patients with Psoriatic Arthritis With and Without Prior Tumor Necrosis Factor Inhibitor Exposure****Mease, P. J. *et al.***

- Date/Time: Sunday November 16th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

9. [1553]: Disease Activity And Clinical Response Early In The Course Of Treatment Predict Long-Term Outcomes In Psoriatic Arthritis Patients Treated With Certolizumab Pegol**Mease, P. J. *et al.***

- Date/Time: Monday November 17th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

10. [1552]: Sustained Improvements in Workplace and Household Productivity and Social Participation with Certolizumab Pegol over 96 Weeks in Patients with Psoriatic Arthritis**Kavanaugh, A. *et al.***

- Date/Time: Monday November 17th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

Presentations on Investigational Studies of Certolizumab Pegol in Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

11. **[852]: Safety and Efficacy of Certolizumab Pegol over 96 Weeks in Patients with Axial Spondyloarthritis, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
Sieper, J. *et al.*
 - Date/Time: Sunday November 16th; 14:30 – 16:00
 - Session Info: Oral Presentation, Exhibit Hall B

12. **[565]: Effect of Certolizumab Pegol over 96 Weeks of Treatment on Inflammation of Spine and Sacroiliac Joints Measured by Magnetic Resonance Imaging in Patients with Axial Spondyloarthritis**
Braun, J. *et al.*
 - Date/Time: Sunday November 16th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

13. **[566]: Structural Progression of the Spine Measured by X-Ray in Patients with Axial Spondyloarthritis Treated with Certolizumab Pegol over 96 Weeks, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
van der Heijde, D. *et al.*
 - Date/Time: Sunday November 16th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

14. **[544]: Observed Incidence Rates of Uveitis Over 96 Weeks of Certolizumab Pegol Treatment in Patients with Axial Spondyloarthritis**
Rosenbaum, J. *et al.*
 - Date/Time: Sunday November 16th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

15. **[543]: Disease Activity And Clinical Response Early In The Course Of Treatment Predict Long-Term Outcomes In Axial Spondyloarthritis Patients Treated With Certolizumab Pegol**
van der Heijde, D. *et al.*
 - Date/Time: Sunday November 16th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

16. **[2560]: Sustained Improvements in Workplace and Household Productivity and Social Participation with Certolizumab Pegol over 96 Weeks in Patients with Axial Spondyloarthritis, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
van der Heijde, D. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

Presentations on Systemic Lupus Erythematosus and Investigational Studies of Epratuzumab

17. **[2834]: Correlation of Laboratory and Clinical Parameters with British Isles Lupus Assessment Group Response in an Open-Label Extension Study of Epratuzumab in Systemic Lupus Erythematosus**
Furie, R. A. *et al.*
 - Date/Time: Tuesday November 18th; 14:45 – 15:00
 - Session Info: Oral Presentation, Boston Convention and Exhibition Center: 205 B

18. **[2873]: Epratuzumab Induces Broad Inhibition of B Cell Receptor Proximal Signaling but Has Opposing Effects on Distal Signaling in B cell Subsets: A Profile of Effects on Functional Immune Signaling by Single Cell Network Profiling**
Maloney, A. *et al.*
 - Date/Time: Tuesday November 18th; 17:30 – 17:45
 - Session Info: Oral Presentation, Boston Convention and Exhibition Center: 109 A

19. **[1077]: A ‘Real-World’ Characterization of US Patients with “Moderate-to-Severe” Systemic Lupus Erythematosus**
Strand, V. *et al.*
 - Date/Time: Monday November 17th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

20. **[1945]: Pharmacodynamic Effects of the CD22-Targeted Monoclonal Antibody Epratuzumab on B cells in Patients with Systemic Lupus Erythematosus**
Shock, A. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

21. **[1942]: Regulation of the Responses of Human B Cell Subsets to Innate Immune Signals by Epratuzumab, a Humanized Monoclonal Antibody Targeting CD22**
Giltiy, N. V. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

22. **[1944]: Targeting CD22 with Epratuzumab Impacts Cytokine Production by B Cells**
Fleischer, V. *et al.*
 - Date/Time: Tuesday November 18th; 8:30 – 16:00
 - Session Info: Poster Session, Exhibit Hall B

23. [1943]: In Vivo Effects of Epratuzumab, a Monoclonal Antibody Targeting Human CD22, on B Cell Function in Human CD22 Knock-In (Huki) Mice
Brandl, C. *et al.*

- Date/Time: Tuesday November 18th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

Presentations numbered 21, 22 and 23 represent UCB collaborations with external research groups.

Presentations on Investigational Studies of Romosozumab in Osteoporosis

24. [916]: Effects of 2 Years of Treatment with Romosozumab Followed by 1 Year of Denosumab or Placebo in Postmenopausal Women with Low Bone Mineral Density
McClung, M. *et al.*

- Date/Time: Sunday November 16th; 16:30 – 16:45
- Session Info: Oral Presentation, 153B

25. [2255]: Vertebral Cortical Bone Mass and Structure Significantly Improved with Romosozumab Compared with Teriparatide: HR-QCT Analyses of Postmenopausal Women with Low BMD from a Phase 2 Study
Damm, T. *et al.*

- Date/Time: Tuesday November 18th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

Presentations on Pregnancy and Rheumatological Conditions

26. [1359]: Care of Women with Rheumatological Conditions during Family Planning and Pregnancy
Clowse, M. *et al.*

- Date/Time: Monday November 17th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

27. [1409]: Pregnancy Outcomes after Exposure to Certolizumab Pegol: Updated Results from Safety Surveillance
Clowse, M. *et al.*

- Date/Time: Monday November 17th; 8:30 – 16:00
- Session Info: Poster Session, Exhibit Hall B

About CIMZIA®

CIMZIA® is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA® has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

Important Safety Information about CIMZIA® in the US

Risk of Serious Infections and Malignancy

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, including Legionella and Listeria.**

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.

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA® is a member. CIMZIA® is not indicated for use in pediatric patients.

Patients treated with CIMZIA® are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic pathogens including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis and tuberculosis have been reported with TNF blockers. Patients have frequently presented with disseminated rather than localized disease.

Treatment with CIMZIA® should not be initiated in patients with an active infection, including clinically important localized infections. CIMZIA® should be discontinued if a patient develops a serious infection or sepsis. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g., corticosteroids or methotrexate) may be at a greater risk

of infection. 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.

Malignancies

During controlled and open-labeled portions of CIMZIA[®] studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate of 0.5 per 100 patient-years among 4,650 CIMZIA[®]-treated patients versus a rate of 0.6 per 100 patient-years among 1,319 placebo-treated patients. 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.

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which CIMZIA[®] is a member. Approximately half of the cases were lymphoma (including Hodgkin's and non-Hodgkin's lymphoma), while the other cases represented a variety of different malignancies and included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

Cases of acute and chronic leukemia have been reported with TNF-blocker use. Even in the absence of TNF-blocker therapy, patients with RA may be at a higher risk (approximately 2-fold) than the general population for developing leukemia.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA[®]. The majority of reported TNF blocker cases occurred in adolescent and young adult males with Crohn's disease or ulcerative colitis. Almost all of these patients had received treatment with the immunosuppressants azathioprine and/or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with CIMZIA[®], especially in these patient types.

Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

Heart Failure

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.

Hypersensitivity

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following CIMZIA[®] administration. Some of these reactions occurred after the first administration of CIMZIA[®]. If such reactions occur, discontinue further administration of CIMZIA[®] and institute appropriate therapy.

Hepatitis B Reactivation

Use of TNF blockers, including CIMZIA[®], has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Test patients for HBV infection before initiating treatment with CIMZIA[®]. Exercise caution in prescribing CIMZIA[®] for patients identified as carriers of HBV, with careful evaluation and monitoring prior to and during treatment. In patients who develop HBV reactivation, discontinue CIMZIA[®] and initiate effective anti-viral therapy with appropriate supportive treatment.

Neurologic Reactions

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 central nervous system demyelinating disease, including multiple sclerosis, and with peripheral demyelinating disease, including Guillain-Barré syndrome. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with CIMZIA[®]. Exercise caution in considering the use of CIMZIA[®] in patients with these disorders.

Hematologic Reactions

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[®]. 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.

Drug Interactions

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. 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.

Autoimmunity

Treatment with CIMZIA[®] may result in the formation of autoantibodies and, rarely, in the development of

a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Immunizations

Do not administer live vaccines or live-attenuated vaccines concurrently with CIMZIA®.

Adverse Reactions

In controlled Crohn's clinical trials, the most common adverse events that occurred in $\geq 5\%$ 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 $\geq 3\%$ 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®, 2% 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® 400 mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving CIMZIA® 200 mg 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.

The safety profile for patients with Psoriatic Arthritis (PsA) treated with CIMZIA® was similar to the safety profile seen in patients with RA and previous experience with CIMZIA®.

The safety profile for AS patients treated with CIMZIA® was similar to the safety profile seen in patients with RA.

For full prescribing information, please visit www.ucb.com

Important Safety Information about CIMZIA® in the EU/EEA

CIMZIA® was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled and open label trials for up to 92 months. The commonly reported adverse reactions (1-10%) in clinical trials with CIMZIA® and post-marketing were viral infections (includes herpes, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopenia (including lymphopenia, neutropenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritus (any sites), hepatitis (including hepatic enzyme increase), injection site reactions, and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy

(includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking CIMZIA[®] due to adverse events vs. 2.7% for placebo.

CIMZIA[®] is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections or moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving CIMZIA[®]. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with CIMZIA[®]. Treatment with CIMZIA[®] must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop CIMZIA[®] if infection becomes serious. Before initiation of therapy with CIMZIA[®], all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, CIMZIA[®] therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with CIMZIA[®]. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with CIMZIA[®].

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including CIMZIA[®] who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with CIMZIA[®]. Carriers of HBV who require treatment with CIMZIA[®] should be closely monitored and in the case of HBV reactivation CIMZIA[®] should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including CIMZIA[®] may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a patient develops any of these adverse reactions, CIMZIA[®] should be discontinued and appropriate therapy instituted.

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with CIMZIA[®].

Adverse reactions of the hematologic system, including medically significant cytopaenia, have been infrequently reported with CIMZIA[®]. 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 haematological abnormalities.

The use of CIMZIA[®] in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, CIMZIA[®] should not be administered concurrently with live vaccines. The 14-day half-life of CIMZIA[®] should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on CIMZIA[®] should be closely

monitored for infections.

CIMZIA[®] was studied in 325 patients with active axial spondyloarthritis (axSpA) in a placebo-controlled clinical trial for up to 30 months and in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled clinical trial for up to 30 months. The safety profile for axSpA and PsA patients treated with CIMZIA[®] was consistent with the safety profile in RA and previous experience with CIMZIA[®].

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision May 2014.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

References

1. CIMZIA[®] US Prescribing Information. Accessed 27th October 2014 from <http://www.ucb.com/>
2. CIMZIA[®] EU Summary of Product Characteristics. Accessed 27th October 2014 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statements - UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those

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